DOCUMENT RESUME

ED 211 876 CG 015 668

AUTHOR Miller, Lillian A.; Alexander, Stephen F.
TITLE Substance Use and Older Persons.
PUB DATE 81
NOTE 105p.
AVAILABLE FROM Northwestern Community Services, P.O. Box 632, Winchester, VA 22601 ($10.50).

EDRS PRICE MF01 Plus Postage. PC Not Available from EDRS.
DESCRIPTORS *Adult Education; *Alcohol Education; Community Education; Community Organizations; Drug Abuse; Drug Education; *Drug Use; *Inservice Education; Instructional Materials; *Older Adults; *Service Workers; Staff Development

ABSTRACT

This guide contains materials developed for senior adults and service providers concerned with substance abuse by the elderly. A module, "Substance Use and Older Persons," is presented in a session-by-session outline of the three one-hour programs. The agenda for the first two sessions focuses on prescription and over-the-counter drugs, while the agenda for the third session concentrates on alcohol education. Use of the module as both an inservice training program for senior center staff members and as an educational program for senior center participants is described. Training session handouts and center presentation handouts are provided along with evaluation forms. Followup materials are provided, including: (1) a three-part article to be used as a handout for participants; (2) center presentation handouts; and (3) a brochure, "Be Responsible for Your Own Health." A one and one-half hour component condensed from the three-hour module for use in senior clubs and other community or civic organizations is outlined. Additionally, a four-hour alcohol awareness module for delivery to residents and staff in a adult home is presented. (NRB)

****
* Reproductions supplied by EDRS are the best that can be made *
* from the original document. *
****

HARD COPY NOT AVAILABLE

ED211876

SUBSTANCE USE AND OLDER PERSONS

Lillian A. Miller
Stephen F. Alexander

Northwestern Community Services
Winchester, VA

1981

U.S. DEPARTMENT OF EDUCATION
NATIONAL INSTITUTE OF EDUCATION
EDUCATIONAL RESOURCES INFORMATION
CENTER (ERIC)

☐ This document has been reproduced as received from the person or organization originating it.

☒ Minor changes have been made to improve reproduction quality.

• Points of view or opinions stated in this document do not necessarily represent official NIE position or policy.

"PERMISSION TO REPRODUCE THIS MATERIAL IN MICROFICHE ONLY HAS BEEN GRANTED BY

Geoffrey K. Byrd

TO THE EDUCATIONAL RESOURCES INFORMATION CENTER (ERIC)."

CG 015668

TABLE OF CONTENTS

PROCESS ..... page 1

THREE HOUR SUBSTANCE USE MODULE 3

DAY 1 5

DAY 2 9

DAY 3 13

TRAINING SESSION HANDOUTS 15

CENTER PRESENTATION HANDOUTS 38

EVALUATIVE MATERIAL 40

FOLLOW-UP 44

1½ HOUR SUBSTANCE USE MODULE 51

FOUR HOUR ALCOHOL AWARENESS MODULE 60

PART I 61

PART II 72

SUBSTANCE USE & OLDER PERSONS

developed by: lillian a. miller, Regional Substance Abuse Prevention Coordinator of Northwestern Virginia

Stephen F. Alexander, Geriatric Specialist, Northwestern Community Services

This package was developed for senior adults and service providers in the Lord Fairfax Planning District. These materials contain a 3-hour module used in training senior center staff as well as for presentation to senior center participants. A 1½-hour presentation was condensed from the 3-hour module in a program for senior clubs and other interested community/civic groups.

In addition, a 4-hour "Alcohol Awareness" component was delivered to residents and staff in an adult home.

available through: Geoffrey K. Byrd, Prevention Director
Northwestern Community Services
P.O. Box 632
Winchester, Virginia 22601
(703) 667-8888

lillian a. miller
Coordinator

Tel. (703) 667-8888
Ext. 28

The "Substance Use and Older Persons" module was developed after a meeting between the Executive Director of the Shenandoah Area Agency on Aging, the Geriatric Specialist of the Northwestern Community Services and the Regional Substance Abuse Prevention Coordinator of Northwestern Virginia. The Center Supervisors were asked to respond to questions pertaining to substance use and abuse in relation to their participants. Their responses were used to develop material that would be relevant.

PROCESS:

I Training Session
II Consultation
III Presentation of Module
IV Evaluation
V Follow-up

I. Training Session

1. Participants - six Center supervisors plus several other staff members

2. Agenda - see page 4

3. A presentation of total module - see pages 5 through 14

4. Handouts - see pages 15 through 35

II. Consultation

Consulted with Center Supervisors and Geriatric Specialist on materials, participation and charting.

III. Presentation of Module

1. Geriatric Specialist presented material in one-hour segments. Day 1 and 2 were presented back-to-back, and Day 3 was presented the following week.

2. Handouts - see pages 36 through 39

3. Geriatric Specialist recorded participation, attendance and own perception of the session's success or failure. A form was developed by the Geriatric Specialsit for this purpose - see page 40

21 SOUTH KENT STREET – P. O. BOX 632 – WINCHESTER, VIRGINIA 22601

IV. Evaluation

1. Evaluation of process by Center Supervisors - see pages 41 and 42

2. Pre and Post Test for participants at the Senior Centers, etc. (or a variation) see page 43

V. Follow-up

1. Geriatric Specialist used materials to develop a three-segment piece for the "Senior Observer", the Shenandoah Area Agency on Aging's monthly newsletter, which ran for three consecutive months - see pages 45 through 50.

2. Geriatric Specialist and Regional Coordinator condensed material to a 1½ hour presentation for other groups i.e., AARP, churches, social/civic clubs, etc. - see pages 51 through 59.

Summary

The training session was presented to six Center Supervisors and some of their staff during a 3-hour training event. The Regional Coordinator and the Geriatric Specialist held (1) consultation session with each Center Supervisor. The module was presented in each center (6). Five of the centers gave three hours (1 hour per day) to the program. The sixth center held the presentation over a 2-day period for 1½ hours per day. Participation in the program from the six centers numbered, on the average, 277 persons. There were approximately 1,572 persons on the "SENIOR OBSERVER" mailing list who were exposed to the follow-up material.

lam
4/80

THREE HOUR SUBSTANCE USE MODULE

THREE HOUR SUBSTANCE USE MODULE

This component has a 2-fold purpose:

(1) training tool for service providers used for a 3 hour in-service training program

(2) educational device for senior center participants who were exposed to the program over a 3 day period, 1 hour per day. Day I and II were delivered on consecutive days, Day III was given the following week

As follow-up to the 3 hour in-service, and prior to the 3 day presentation, Consultation was provided for individual center adaptation of the material.

The Evaluative process contained 3 pieces:

(1) Presenter's Appraisal

(2) Service Provider's Evaluation

(3) Participant Pre and Post Questionnaire

Follow-up included:

(1) a 3-segment article printed in the monthly newsletter of the Shenandoah Area Agency on Aging

(2) the development of a brochure, "Be Responsible for Your Own Health"

(3) a Substance Use information booth at the Senior Citizens Services Council Annual May Picnic

SUBSTANCE USE AND OLDER PERSONS

Day I Prescription and Over the Counter (OTC) Drugs

1. An Overview: Some Facts
2. Some Factors Contributing to Misuse
3. Introduction: Elder-Ed Film - "Wise Use of Drugs" NIDA (301)443-6500
4. Response/Reaction to Film
5. The Body and Drugs
6. Aspects of Drug Misuse Commonly Implicated in Drug Problems
7. Drug Interactions
8. Discussion

Day II Prescription and Over the Counter (OTC) Drugs

1. Recap Drug Interactions
2. Walk Through Elder-Ed Materials
   - A. Tips: DOs and DONT's
   - B. Questions to Ask Doctor/Pharmacist
   - C. Making Charts

Day III Alcohol Education

1. An Overview: Some Facts
2. Some Factors Contributing to Misuse
3. Alcohol and Drug Interactions
4. Discussion on Alcohol
5. Film
6. Discussion

Day I Prescription and Over the Counter Drugs

1. An Overview: Some Facts

approximately 22 million (or 11%) of the population is 65 and over
fastest growing population
80 - 86% suffer at least one chronic condition
consume 25% of all prescription drugs
aging process contributes to risk of drug side effects
no specific geriatric drug doses
helping professions usually are uninformed about aging process and its implications
discrimination and stereotyping
side effects of drugs usually attributed to aging
women consume more legal drugs than men
older woman living alone is at highest risk of most vulnerable

2. Some Factors Contributing to Misuse

society's general acceptance of "pills" as a cure-all
over-prescribing of doctors
lack of re-evaluation of medicines
sedatives, tranquilizers and anti-depressants used in combination
fixed income contributes to extensive OTC drug useage
fear of doctors
lack of transportation
use of legal drugs to cope with daily life
    stress
    self-esteem
    self-concept
    loneliness
    inactivity

3. Introduction: Elder-Ed Film - "Wise Use of Drugs" NIDA - (301) 443-6500

4. Response/Reaction to Film

5. The Body and Drugs

PHYSIOLOGICAL CHANGES ASSOCIATED WITH AGING
WHICH INCREASE THE RISK OF DRUG PROBLEMS

CHANGES	RISKS
tendency to multiple and chronic pathologies	greater drug use, increase risk of reactions
reduced circulatory, digestive, liver and kidney functions	slower utilization, risk of toxicity when standard drug dosage applied

CHANGES	RISKS
changes in function such as sleeping and elimination	tendency to mis-use OTC drugs to correct these conditions
decreased rates of absorption, excretion and metabolism	danger of side effects or negative reactions
changes in vision and hearing	difficulty in comprehending instructions, risk of misadministration
short-term memory loss	risk of under or over administration

PSYCHOLOGICAL STATES WHICH INCREASE THE RISK OF DRUG MISUSE

PSYCHOLOGICAL STATES	POSSIBLE PROBLEMS
lessened tolerance for change and disruption	tendency to rely on "tried and true" regimens that may be ineffective or may delay a needed visit to the doctor
fear of loss of independence	refusal to take drugs
feelings of insecurity, need for reassurance	ritualistic dependence on regimens, drugs
feelings of uselessness, worthlessness	projection onto body of emotional symptoms associated with drug treatment
reactions to grief and loss	(mis)use of antidepressants and mood elevating drugs
over-introspection leading to increased body consciousness	associated drug treatment
feelings of boredom, lack of stimulation	use of drugs to structure time, overuse of sleeping medications

6. Aspects of Drug Misuse Commonly Implicated in Drug Problems

Drug Problems	Aspects of Misuse
Overuse	Mistaking, forgetting, taking another
Underuse	Mistaking, failure to fill prescription, discontinuing use, forgetting to take
Improper Use	Failure to follow time, diet, other requirements, incorrect storage, use of outdated drugs, sharing and borrowing of drugs, failure to moniter side effects, taking duplicate medicines prescribed by different doctors, interactions between regularly used items: nicotine, caffeine and decongestants, normal adult doses are imappropriate for some older persons
Abuse	Habituation, use for suicide

7. Drug Interactions

PRESCRIPTION DRUGS

Avoid consuming these drugs in combination with one another

antibiotics	
tetracyclines	gelusil antacid tablet
penicillin	aspirin
neomycin or streptomycin	ether
percodan	narcotic analgesics tranquilizers general anesthesia
valium	CNS - depressant drugs barbiturates
barbiturates	Vitamin C anticoagulants antacid
anti-depressants	hormones - estrogen Vitamin C
narcotic analgesics	antihistamines
codeine	muscle relaxants
anticoagulants	diuretics
diuretics	Vitamin K - leafy green vegetables

antihistamines

hormones - estrogen
orinase (anti-diabetic agents)

Aspirin inhibits the effectiveness of Vitamin C.

Some heart meds may interact with anti-coagulants, anti-convulsants, and anti-tubercular medicines.

Valium - as little as 2 - 2 1/2 mg (1 to 2 times daily) to prevent over sedation in older people.

Diuretics - may need to increase potassium intake through foods or coated tablets.

Percodan - habit forming, elderly are special risk patients.

Dilantin - severe complications may appear in older persons.

Anti-depressants - Elavil - low doses for elderly persons.

OVER THE COUNTER DRUGS

Avoid consuming these drugs in combination with one another

Aspirin inhibits the effectiveness of Vitamin C

antihistamines
- Allerest
- Coricidin

analgesics
- aspirin
- Cope

mineral oil
- oral consumption

Vitamins A, D, E, K

Vitamin C

aspirin

Alka-Seltzer - do not use on sodium restricted diet

Sinutab - use with caution with thyroid and heart disease, hypertension and diabetes

Tylenol
Bufferin
Aspirin
potential for overdose

Vitamin E - may cause hemorrhage in Vitamin K deficient patients

Vitamin D - potential for overdose

Robitussin - use with caution with diabetes, hypertensive and cardiac disorders

Alka-Seltzer Plus - use with caution with high blood pressure, diabetes, heart and thyroid disorders

(for additional information on Interactions see page 58)

Day II Prescription and Over the Counter Drugs

Day II Prescription and Over the Counter Drugs

1. Recap Drug Interactions

2. Walk Through Elder-Ed Materials

A. Tips: DOs and DON'Ts

Do: ask questions
something daily that helps relax
check with doctor - how long to take prescription
tell doctor about other medicines, OTC's and special diets
eat properly - drink plenty of water
exercise daily
ask pharmacist about generic drugs
ask pharmacist about drug interactions
follow doctor's directions
ask pharmacist about a drug's expiration date
ask doctor for a simple drug taking schedule to fit daily activities
let doctor know of any/all side effects
tell doctor about symptoms and allergies
ask for easy-open caps

Don't: drink alcohol when taking medicine
drink alochol to make you feel better
stop taking medicines without doctor's advice
stop taking medicines because you feel better
take vitamins without telling doctor
use OTC's regularly or for long periods of time
take added dose to make up for missed dose
use medications of others
take medicines in the dark
share medications with others
use old prescriptions
dismiss side effects as signs of "old age"
mix medications in one bottle or transfer from one bottle to the other

B. Questions to ask doctor/pharmacist

1. What is being prescribed?
2. What is it supposed to do?
3. How will it make me feel?
4. How long do I take it?
5. What food or medications can/can't take with new prescription?
6. How do I take it?
with/without water?
with/without food
before, after or with meals
7. How often?

C. Making Charts

Center supervisors identified those charts that were applicable to the needs of senior center participants. In some cases, these were modified to take into consideration an individual's reading level.

The "Medicines I Take" chart can be used to inform an individual's personal physician of his/her drug status. To further heighten awareness of drug useage, participants may bring medicines and OTC's to the senior center for charting.

The "Times for Taking Medicines" chart is self-explanatory.

MEDICINES I TAKE			
NAME OF MEDICINE	DR./PHARMACIST	WHAT MEDICINE IS FOR	DIRECTIONS
DRUG A	DR. BROWN	symptom 1	before breakfast
DRUG B	DR. BROWN	symptom 2	before ea. meal
DRUG C	DR. Smith	symptom 3	8:00 a.m.
Aspirin	CORNER DRUGS	headaches	as needed
Antacid	CORNER DRUGS	heart burn	as needed
Vitamin C	CORNER DRUGS	supplement	one per day

MEDICINES I TAKE			
NAME OF MEDICINE	DR./PHARMACIST	WHAT MEDICINE IS FOR	DIRECTIONS

Day III Alcohol Education

1. An Overview: Some Facts

- abuse in older population probably exceeds 3 million persons 60 years of age and older
- identified as most serious abuse problem among aging persons
- little is known about special needs of this age group
- public inebriates contain disproportionate numbers of older persons
- problems of abuse usually undetected
- alcoholism may not be diagnosed by medical personnel
- 2 types of alcoholism: a) reactive - coping mechanism
  b) life-long pattern of dependency
- contributes to a number of falls in older population
- high incidence of alcohol abuse in nursing homes and homes for adults
- may mask other problems; i.e., depression
- widowers are the highest at risk group

2. Some Factors Contributing to Abuse

- denial - older person
  family
  medical people
  social service agencies
- bias of treatment service providers - some older people have other kinds of physical problems that complicate treatment and many facilities are not equipped to handle such problems
- social factors - death of loved ones
  retirement
  isolation
  new roles
  fixed income
  loneliness
- myth of untreatability - believes older person is more set in ways, will not/cannot change; therefore treatment emphasis is placed on young who have a higher recovery rate

MEDICINE	DIRECTIONS & CAUTIONS	TIMES FOR TAKING MEDICINES						
		SUN	MON	TUES	WED	THUR	FRI	SAT
DRUG A	before meals	~~7 12~~ 5	~~7 12~~ 5	~~7 12~~ 5	~~7 12~~ 5	7 12 5	7 12 5	7 12 5
DRUG B	before breakfast keep in air-tight container	~~7~~	~~7~~	~~7~~	~~7~~	7	7	7
DRUG C	before retiring for bed - don't drink w/ milk	~~10~~ P.M.	~~10~~ P.M.	~~10~~ P.M.	10 P.M.	10 P.M.	10 P.M.	10 P.M.
DRUG D	at Noon Meal	~~12~~	~~12~~	~~12~~	~~12~~	12	12	12

MEDICINE	DIRECTIONS & CAUTIONS	TIMES FOR TAKING MEDICINES						
		SUN	MON	TUES	WED	THUR	FRI	SAT

3. Alcohol and Drug Interactions

Medication	Action	Risk
Penicillin	Direct interaction in stomach	Lowers blood level of penicillin
Aspirin	Interferes with clotting	Gastrointestinal bleeding
Percodan	Impairs physical and mental abilities	Increase CNS depression
Anesthetics	Reduces metabolism rate of other drugs	Increases anesthesia for dry alcoholics
Opiates (Morphine)	Depression of functions	Increases CNS depression
Stimulants (Amphetamines) (Caffeine) (Nicotine)	Stimulates	Increases deterioration of performance
Antihistamines	CNS action (confusion) (restlessness) (deterioration)	Deteriorates driving performace
Sedatives (Barbituates) Seconal Tuinal (Non-Barbituates) Dalmane	Increases CNS depression	Combination may cause death
Tranquilizers (Librium) (Valium)	Increases CNS depression	Combination may cause death
Anticoagulants	Should not be taken with any other drug - whether prescription or OTC without doctor's knowledge	Alters response to anticoagulant, enhances effect which may lead to bleeding
Cough medicines	Increases CNS depression	Serious hazard, may cause death
Anti-hypertensive medications		Fainting spells and loss of consciousness

4. Discussion on Alcohol

5. Film "Wise Use of Drugs" (Elder-Ed) or any appropriate film of your choosing

20

6. Discussion

TRAINING SESSION HANDOUTS

Side Effects and Cautions for Commonly Used Drugs

MEDICATION	NOTES
Decongestants and over-the-counter cold remedies	Persons with high blood pressure, heart disease, thyroid disease or glaucoma should take only upon advice of their physician.
Sulfa Drugs (Gantrisin, Azo-Gantrisin) For urinary tract infections	Patient should drink large amounts of fluids. Avoid prolonged exposure to direct sunlight.
Penicillins (Ampicillin, Amoxicillin) Antibiotics for infections	Take on an empty stomach for quick absorption. Always take entire amount dispensed unless told otherwise by the physicians.
Anthihistamines (Benadryl, Chloritrimeton) for allergies	Common side effects are drowsiness; sometimes dryness of the mouth, blurred vision and difficulty in urination.
Tranquilizers (Valium, Librium, Haldol)	May cause drowsiness. Patients should use caution in driving or operating machinery. Alcohol may intensify the effect of these drugs.
Antidepressants (Elavil, Aventyl, Sinequan) "Mood Elevators"	Dry mouth, blurred vision and constipation are sometimes noted. Drowsiness is the most common side effect and use of alcohol may increase this effect.
Multivitamins	Take with water. Do not take with mineral oil, which prevents the absorption of Vitamins A, D and E.
Diuretics (Hydrodiuril, Hygroton) For excess fluids	Some diuretics can cause loss of potassium. In addition to a good diet, patients should increase the intake of potassium-rich foods, such as bananas, citrus foods, melons and tomatoes.
Nitroglycerin For chest pains in heart patients	To prevent loss of potency of the drug, patients should keep tablets in their original container. Close tightly immediately after each use.
Tetracyclines (Sumycin, Achromycin) Antibiotic for infections	Avoid taking antacids or dairy products within 1 hour before or 2 hours after the medication, as these products interfere with the absorption of the drug. Prolonged exposure to direct sunlight could result in a severe sunburn.
Erythromycin (Erythrocin, E.E.S.) Antibiotic for infections	Avoid taking with fruit juices, since the acidity may destroy the erythromycin or the special coating on some products.
Pyridium, Azo-Gantrisin, Azulfidine Pain relievers for urinary tract	Usually cause a red or orange coloration of the urine which, when due to this medication, is of no medical consequence.
Stool Softeners (Colace, Peri-Colace, Surfak)	Take with water. Do not take with mineral oil, which interferes with the action of the stool softeners.

EXTENSION EXTRAS

Talking with The Pharmacist

By JUDY BURTNER
Frederick County Extension Agent

The Food and Drug Administration in April published some information on how to talk with and listen to your pharmacist. They recommended that the relationship between you and your pharmacist should be just as close as the one between you and your doctor.

Today, drugs are so expensive that it is important that you take them in such a manner that you will get the most benefit for your money. Your doctor may have told you, but such instructions are sometimes forgotten when you're upset or ill. Often the label on the bottle is not much help. "Take As Directed" or "Take As Needed" is too vague. "Take 4 times a day" isn't much more specific and "take with meals" could be misleading if your ulcer treatment calls for six small meals instead of the standard three.

YOUR PHARMACIST can advise you on the exact time you should take that medicine in order to get the most benefit from it. You should ask whether your drug can be taken with food or if certain foods or beverages should be avoided. For instance, washing the antibiotic tetracycline down with a glass of milk can greatly reduce the effectiveness of that medication. Some drugs must be taken with a full glass of water. Soda pop or fruit juices may be alright to ease the passage of some tablets, but they may be the wrong liquid for others.

Another important question you should ask your pharmacist is whether you can expect any side effects from your medicine. For instance, you will want to know whether a drug will make you drowsy and how long this effect will last. This information is important if you have to perform tasks such as driving or operating machinery that requires you to be alert. Ask too, whether it is alright to have a cocktail or wine with dinner. Alcohol is a depressant and even a small amount can increase the depressant effect of such drugs as tranquilizers and antihistamines.

How to store your medicine is more important than people realize. Putting a bottle of medicine on the kitchen window ledge may be a handy way to remember to take it, but light may cause it to deteriorate. On the other hand, the bathroom medicine cabinet is misnamed.

It is not a good place to store drugs because of the moisture generated by steam from the bath or shower. Some medicine should be kept cool and dry; some should be refrigerated. Your pharmacist can advise you of the best way to store your medicine to insure that it doesn't lose its effectiveness.

IF YOU ARE on a medication schedule that calls for a dose during the day and you have to work, don't put a small supply of tablets in a pill box even though it is more convenient. The tablets may break apart in which case you may not get the correct dose. Or, they could react with the metal the box is made of. Or in some cases, such as nitroglycerin, they can be absorbed by plastics. In such cases, the pharmacist can place your medications in smaller containers.

Even though over-the-counter drugs are readily available on open shelves for the consumer to pick and choose, it's a good idea to discuss your selection with the pharmacist. This is particularly true if you are taking prescription drugs over a long period of time.

The pharmacist can steer you away from OTC preparations that contain aspirin if he knows that you are taking an anti-coagulant to thin the blood (aspirin increases bleeding). He can tell you what drugs to avoid if you are allergic to other drugs or should avoid substances such as sodium.

Another area that can be discussed with your pharmacist is the matter of "generic drugs." Substituting generic drugs for a brand name drug can mean a big savings.

The pharmacist can not prescribe, only a physician can; however, he can interpret the physician's decisions. It is important to remember that he or she can be an excellent source of information. All you have to do is ask.

Drugs Can Interact With Various Foods

EXTENSION EXTRAS

By JUDY BURTNER
Frederick County Extension Agent

If you take any kind of drugs regularly—and that means over-the-counter (OTC) preparations and alcohol as well as prescribed drugs — what you eat and when is more important than you may think.

According to Daphne A. Roe, M.D. and professor in the Division of Nutritional Sciences, N.Y. State Colleges of Agriculture and Life Science and Human Ecology at Cornell, the American public is "extremely uninformed" about the adverse effects of drugs in general and particularly about the effects of drugs on nutritional status.

FOODS CAN HINDER the absorption of drugs into the boodstream, or interest with drugs to produce unexpected effects; similarly, drugs can interfere with the absorption of nutrients of the body's ability to convert nutrients into usable form.

Sometimes these interactions are intended, as with the prescription of anticoagulants, which impede the action of vitamin K, for the patient with a tendency toward blood-clotting. Unintended reactions, however, can cause problems, lowering nutrient levels or counteracting a drug's therapeutic purpose.

A number of common OTC drugs can affect nutritional status. Large doses of aspirin, for instance, can cause erosions in the lining of the stomach that bleed and may result in iron deficiency anemia. Phosphate depletion from heavy unsupervised use of antacids can produce muscle weakness and vitamin D deficiency. Even mineral oil, which many think of as a natural and harmless laxative, can decrease the body's absorption of the fat-soluble vitamins A, D, E and K.

Prescribed drugs may also interact with nutrients in unplanned ways, and dietary adjustments may have to be made. In some cases, it is necessary only to avoid certain foods at the time the drugs are taken. Milk, for example, inhibits the action of tetracycline.

With other drugs, however, more significant dietary changes may be necessary. Since oral contraceptives lower blood levels of folic acid and vitamin B6, it is important that women who take them eat green leafy vegetables, nuts, whole grains, and other sources of the nutrients that may be lost. Roe points out that these deficiencies do not usually occur in women who eat well-balanced diets, but may cause problems for those who live on snack foods.

EXCESSIVE USE of both OTC and prescription drugs by the elderly makes them particularly likely to incur drug-related nutritional problems. "In the United States, the elderly are the chief drug users — they are very highly at risk," says Roe.

Older persons may have chronic diseases or handicaps that prompt them to use drugs, and nutrient reactions can be complicated by inadequate food intake due to living circumstances, depression, or lack of appetite caused by disease. Over-medication is also a problem, particularly in extended care facilities, where absentee physicians and inadequate chart review can lead to the prescription of multiple drugs for a single medical problem.

To reduce the likelihood of drug-induced malnutrition, an individual should eat foods that will provide needed nutrients. Because vitamin supplements in high dosage can interfere with the effectiveness of drugs, it is better to eat needed vitamins and minerals from foods.

It is also very important that the patient get detailed instructions from the physician and pharmacist on when and how to take prescribed drugs, including information on necessary dietary adjustments.

Frequent use of OTC preparations, particularly by an individual who is taking prescribed drugs, is not advisable; a patient should read label information and warnings and check use of any unprescribed drugs with a doctor.

Growing children, the elderly, and pregnant women are vulnerable to drug caused nutritional problems. Other people at risk include those with poor diets, chronic health problems, or people taking drugs for extended periods of time.

Generic Drugs: How Good Are They?

ge•ner•ic *adj* [fr. L *gener-, genus*, birth, race, class, kind + F *-ique* -ic — more at KIN] **a:** common to or characteristic of a whole group or class **b:** available for common use: not protected by trademark registration: NONPROPRIETARY (nylon and aspirin are generic names)

"Generics" is a term that is heard frequently today, often in connection with consumer products that are sold without a brand name or fancy labeling. What does this term mean when it is used in reference to prescription drugs?

When a new drug is first developed, it is usually patented and sold exclusively under a single brand name. Drug patents run 17 years. During the time of this exclusive marketing, the brand name of this first drug becomes well known. Such original drugs are often referred to as "brand name" drugs. If there is no patent or after a patent has expired, other firms may manufacture and sell the drug either under different brand names or under the drug's generic name, as in the second meaning of the word (above). These exact copies of the original drug are often called generic drugs.

The generic name, also called the "official" or "nonproprietary" name, is often descriptive of the chemical composition or class of the drug and is assigned to the drug in the early stages of its development. Thus, every drug has a generic name.

Tetracycline, for instance, is the generic name for a widely used antibiotic. A physician may write a prescription for this drug by the generic name or by one of several brand names, such as Achromycin, Sumycin, or Tetracyn. Or, as another example, chlordiazepoxide hydrochloride is the generic name for a minor tranquilizer. Most consumers know this drug as Librium, the brand name of the original drug. Today there are many generic chlordiazepoxide products, many marketed under the generic name, and a few under various brand names. Brand names are prominently used in advertising a drug to the medical profession, although the generic name must appear in advertising and labeling in letters at least half as big as that of the brand name.

There is a popular misconception that brand name drugs are produced only by large, well-known firms, while generics are made by small, unknown companies. Actually, about 90 percent of all generic drugs are made by the major

ug firms in the country, the ones who also develop the "brand name" drugs. Many small drug companies put a brand name on their products, just as many large companies market their generic drugs under the generic name. Some large firms even distribute, under their brand names, products that have been manufactured, packaged, and labeled by smaller firms that make only generic drugs.

Are generic drugs as good as the brand name products? The answer to that frequently asked question is yes, when the drugs have been approved by the Food and Drug Administration for safety and effectiveness and can be expected to behave in the same way in the body.

In some instances, however, marketed drug products have been found to have "bioequivalence" problems. This means that products containing the same drug ingredient made by different manufacturers may differ in the rate at which the active ingredient is absorbed in the body, and hence differ in the rate at which the drug does its job. Where such differences exist, the drugs cannot be considered "therapeutically equivalent" and they should not be substituted for one another.

General recognition that there were identical drugs with bioequivalence problems did not come until the late 1960's. Discovery of these problems was delayed, in part because of the lack of sensitive scientific equipment and testing methods necessary to detect small quantities of drugs in the blood. Because of the difficulty in developing these sensitive tests, the means for determining bioequivalence is not yet available for all drugs. Since 1970, FDA has required New Drug Applications to include appropriate scientific evidence of bioequivalence for those drugs posing a potential bioequivalence problem. FDA is continuing its efforts to assure that all multi-source drugs (drugs available from more than one manufacturer) are therapeutically equivalent, whether they are brand name or generic.

Early in 1979, FDA drafted a list of the more than 5,000 prescription drug products approved for marketing in the United States. These account for about 75 percent of the money spent on prescription drugs. About one-third of the drugs in this list are available only from one manufacturer because of patents or because the drug is of little commercial value. There are no substitutes for such drugs at this time. Of the 3,330 approved drug products available from more than one manufacturer, more than three-quarters—about 2,400—are considered therapeutically equivalent to other products of the same drug, dosage form, and strength. They do not necessarily look or taste alike, however. Drug products in the approved drug list are coded so that users of the list can determine which products are therapeutically equivalent and, therefore, can be substituted for one another. FDA intended that this preliminary list could be used by State officials in preparing their lists for use by pharmacists in determining which generic drugs can be safely substituted. A final version of the FDA list is now being prepared.

Whether they are brand name products or generic versions, all approved drugs must meet the same FDA standards of quality. All drug manufacturing firms, large and small, must register with FDA. All are subject to periodic inspection. All must follow FDA's Good Manufacturing Practice Regulations that touch on every aspect of drug manufacture from building maintenance to quality control.

Another assurance of drug quality stems from FDA's monitoring programs. FDA periodically collects samples of all drug products, both generic and brand name, from manufacturers and from the marketplace to be tested in the Agency's laboratories for purity and strength. Automated equipment in these labs permits rapid analysis of large numbers of drug samples. When defects are found, the drug company is notified and appropriate measures are taken to remove the defective products from the market.

Testing and certification is required by law for insulin and antibiotics and for biological products, such as serums and vaccines. Even when FDA discovers major industry-wide problems with drugs other than antibiotics or insulin, it may ask manufacturers to have each batch of that drug certified by the Agency before it is released for sale.

FDA's effort to assure the quality and therapeutic equivalence of drugs should be of more than passing interest to consumers, for it concerns their wallets as well as their health. Generics generally are less expensive than their brand name equivalents. Thus, consumers—especially those who must take drugs for long periods of time—may be able to save money by asking their physicians to prescribe their medication generically if it is possible to do so.

Generic prescribing has been on the rise during the past decade. A national audit of prescriptions filled in retail pharmacies showed that over 101 million new generic prescriptions were dispensed in 1978, more than 13 percent of the total new prescriptions for that year. In 1966 new generic prescriptions accounted for only 6.4 percent of the total.

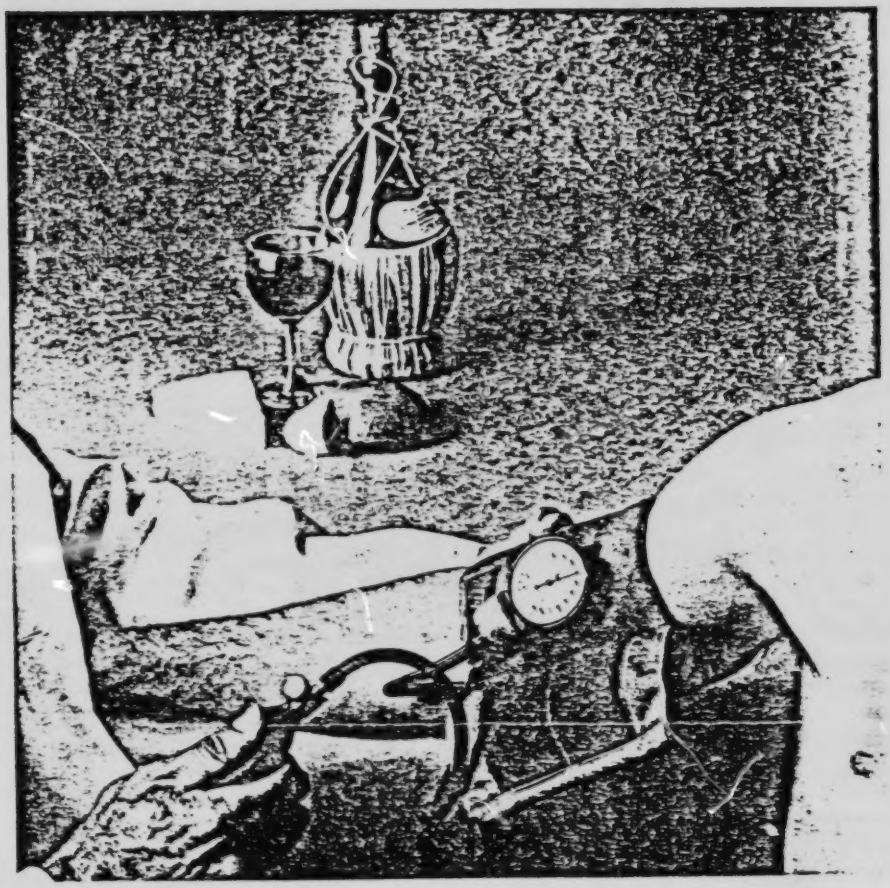
Of the 200 drug products most frequently prescribed in 1978, 17 were generic products. Of these, 7 ranked in the top 50. Antibiotics are at the head of the list of the 20 leading generic drugs. New prescriptions for the 6 most popular generic antibiotics totaled well over 57 million in 1978, 58 percent of all new generic prescriptions for that year.

Generic prescribing may increase in the future as a result of action by most States to repeal laws that forbade pharmacists from dispensing any version of a drug product other than that specifically prescribed by the doctor. Under these old laws, if a doctor prescribed a certain brand of a drug a pharmacist could not substitute the same product from another manufacturer although it may have cost less and was the chemical "twin" of the prescribed brand. Only a few States still have these so-called antisubstitution laws. Most States that have repealed them now permit the pharmacist to choose a substitute product unless the physician says that substitution would not be in the best interests of the patient.

The following table lists the 14 most often prescribed drugs that are available generically. If you are taking one of these drugs under a brand name, it may save you money to ask your physician to write a generic prescription instead. There may be a sound medical reason that your doctor prefers a brand name. But if not, you should have the opportunity to save on the cost of your prescription while still getting essentially the same product. Remember, this list is of only the most frequently prescribed drugs. Many others also have generic equivalents. So whenever your doctor writes a prescription, ask if the drug is available generically.

Generic Name	Commonly Prescribed Brand Names	Purpose of Drug
Ampicillin	Amcill Omnipen Polycillin Principen	To fight infection (antibiotic)
Tetracycline	Achromycin V Panmycin Sumycin Tetracyn	To fight infection (antibiotic)
Acetaminophen/codeine	Tylenol with Codeine	To relieve pain, fever, and cough
Hydrochlorothiazide	Esidrix HydroDIURIL Oretic	For hypertension and edema (diuretic)
Penicillin V-K	Pen-Vee K V-Cillin K Veetids	To fight infection (antibiotic)
Chlordiazepoxide hydrochloride	Librium	To relieve anxiety and tension
Propoxyphene hydrochloride, aspirin, phenacetin, and caffeine	Darvon Compound-65	To relieve pain (analgesic)
Erythromycin stearate	Erythrocin Stearate	To fight infection (antibiotic)
Amitriptyline hydrochloride	Elavil Endep	To relieve symptoms of depression
Diphenhydramine hydrochloride	Benadryl	Antihistamine (also for motion sickness and parkinsonism
Diphenoxylate hydrochloride with atropine sulfate	Lomotil	To help control diarrhea
Meclizine hydrochloride	Antivert	To control nausea and vomiting, and dizziness from motion sickness
Chlorothiazide	Diuril	For hypertension and edema (diuretic)
Erythromycin ethyl succinate	E.E.S.	To fight infection (antibiotic)

Perhaps the most hazardous food-drug interaction is the one between monoamine oxidase (MAO) inhibitors, drugs often prescribed for depression and high blood pressure, and such foods as aged cheese, Chianti wine, and chicken livers.



alertness. A good rule of thumb is to avoid alcoholic beverages when taking any type of prescription or over-the-counter medication.

Just as some foods can affect the way drugs behave in the body, so some drugs can affect the way the body uses food. Drugs may act in various ways to impair proper nutrition: by hastening excretion of certain nutrients, by hindering absorption of nutrients, or by interfering with the body's ability to convert nutrients into usable forms. Nutrient depletion of the body occurs gradually, but for those taking drugs over long periods of time these interactions can lead to deficiencies of certain vitamins and minerals, especially in children, the elderly, those with poor diets, and the chronically ill.

Some drugs inhibit nutrient absorption by their effect on the bowel wall. Among these are colchicine, a drug prescribed for gout, and mineral oil, an ingredient used in some over-the-counter laxatives.

A number of drugs affect specific vitamins and minerals. The antihypertension drug hydralazine and the antituberculosis drug INH can deplete the body's supply of vitamin B_6 by inhibiting production of the enzyme necessary to convert the vitamin into a form the body can use or by combining with the vitamin to form a compound that is excreted.

Similarly, anticonvulsant drugs that are used to control epilepsy can lead to deficiencies of vitamin D and folic acid because they increase the turnover rate of these vitamins in the body.

Quite a few drugs—for example, colchicine, oral antidiabetic agents, and the antibiotic neomycin—can

Food And Drug Interactions

If you're taking a drug, the food you eat could make it work faster or slower or even prevent it from working at all. Eating certain foods while taking certain drugs can be dangerous. And some drugs can affect the way your body uses food.

by Phyllis Lehmann

Would it occur to you not to swallow a tetracycline capsule with a glass of milk? Or to avoid aged cheese and Chianti wine if you are taking a certain medicine to combat hypertension? Or to eat more green leafy vegetables if you are on The Pill? Probably not. Yet the effects foods and drugs have on each other can determine whether medications do their job and whether your body gets the nutrients it needs.

The extent of interaction between foods and drugs depends on the drug dosage and on the individual's age, size, and specific medical condition. In general, though, the presence of food in the stomach and intestines can influence a drug's effectiveness by slowing down or speeding up the time it takes the medicine to go through the gastrointestinal tract to the site in the body where it is needed.

Food also contains natural and added chemicals that can react with certain drugs in ways that make the drugs virtually useless. Some reactions can be downright dangerous, triggering a medical crisis or, in rare instances, even death.

It is because of these interactions that your doctor tells you to take certain medications on an empty stomach, some just before meals, and some with meals.

A major way food affects drugs is by enhancing or impeding absorption of the drug into the bloodstream. There are a few cases in which foods speed up absorption. For example, blood levels of griseofulvin, a substance that combats fungus infections such as ringworm, rise markedly if the patient eats fatty foods before taking the drug.

More commonly, though, food and beverages interfere with absorption. A classic interaction is the one between tetracycline compounds and dairy products. The calcium in milk, cheese, and yogurt impairs absorption of tetracycline. On the other hand, taking some iron supplements with citrus fruits or juices which contain ascorbic acid enhances absorption of the iron.

In general, it is unwise to take drugs with soda pop or acid fruit or vegetable juices unless you check with your doctor first. These beverages can result in excess acidity that may cause some drugs to dissolve quickly in the stomach instead of in the intestines where they can be more readily absorbed into the bloodstream.

Some foods contain active substances which can cause a drug effect or which can interact with a drug to produce an unexpected or counter effect. For example, licorice extracted from natural sources contains a substance which, when consumed regularly in excess amounts, may cause an elevation in blood pressure. Licorice is a favorite ingredient in candy and a flavoring for some pharmaceuticals. Most American manufacturers now use a synthetic flavoring but many imported products still contain licorice from natural sources. Continued regular use of products containing natural licorice extract could aggravate high blood pressure or counteract the effect of medication for high blood pressure.

Excessive consumption of foods high in vitamin K, such as liver and leafy green vegetables, may hinder the effectiveness of anticoagulants. Vitamin K, which promotes clotting of the blood, works in direct opposition to these drugs, which are intended to prevent clotting.

Some foods, such as soybeans, rutabagas, brussels sprouts, turnips, cabbage, and kale, contain substances known as goitrogens which inhibit production of the thyroid hormone and thus can produce goiter. Scientists suggest caution in eating these foods when taking thyroid medications.

Perhaps the most hazardous food-drug interaction is the one between monoamine oxidase (MAO) inhibitors, drugs at times prescribed for depression and high blood pressure, and such foods as aged cheese, Chianti wine, and chicken livers. MAO inhibitors can react with a substance called tyramine in these foods and force the blood pressure to dangerous levels, sometimes causing severe headaches, brain hemorrhage, and, in extreme cases, death.

To prevent a possible reaction, anyone taking MAO inhibitor drugs should avoid aged and fermented foods, including pickled herring; fermented sausages, such as salami and pepperoni; sharp or aged cheeses; yogurt and sour cream; beef and chicken livers; broad beans, such as fava beans; canned figs; bananas; avocados; soy sauce; active yeast preparations; beer; Chianti wine, sherry, and other wines in large quantities. MAO inhibitors also are suspected of reacting adversely with cola beverages, coffee, chocolate, and raisins.

Alcohol, which is actually a drug itself, although not regulated as a drug under the Food, Drug, and Cosmetic Act, does not mix well with a wide variety of medications, such as antibiotics; anticoagulants; antidiabetic drugs, including insulin; antihistamines; high blood pressure drugs; MAO inhibitors; and sedatives. Alcohol combined with antihistamines, tranquilizers, or antidepressants causes excessive drowsiness that can be especially hazardous to someone driving a car, operating machinery, or performing some other task that requires mental

impair absorption of vitamin B_{12}. But because most Americans have good stores of B_{12} in their livers, it takes prolonged ingestion of these drugs to cause a deficiency.

Long term use of diuretics, or "water pills," to treat such conditions as congestive heart failure, can lead to serious potassium depletion. If the potassium loss is not corrected in heart patients taking digitalis, the heart may become more sensitive to the effects of the drug. People taking diuretics regularly should eat foods which are good sources of potassium. These include tomatoes and tomato juice, oranges and orange juice, dried apricots, cantaloupes, figs, raisins, bananas, prunes, potatoes, sweet potatoes, and winter squash.

Modifying the diet to include more foods rich in the vitamins and minerals that may be depleted by certain drugs generally is preferable to taking vitamin or mineral supplements. In fact, supplements of some vitamins can counter the effectiveness of certain drugs.

Fortunately, the diets of most Americans are sufficiently well-balanced so that the threat of drug-related nutritional deficiencies can be easily overcome.

Because oral contraceptives are used so widely, their effect on nutrition has been getting increasing attention. The Pill is known to deplete the blood's content of certain vitamins, notably folic acid and vitamin B_6, but usually the vitamin depletion is not serious enough to cause overt symptoms. In most healthy women with good diets, these vitamin levels do not go down to a point that is alarming, says Dr. Daphne Roe, a Cornell University nutritionist. "But in a poverty group of young women who are trying to make do with very little and who have limited nutritional knowledge, you may find a different situation," Dr. Roe says. "It is this group we are most concerned about."

Because her requirements for several vitamins may be increased, it is especially important for any woman on The Pill to eat a nutritionally balanced diet. In particular, if a woman on The Pill is living on snack foods, she is more likely to develop folate deficiency than her neighbor who every day eats green leafy vegetables, which are a good source of folic acid, according to Dr. Roe.

Drugs readily available without prescription also can lead to nutritional problems. The worst offenders are antacids, Dr. Roe says, because they are so widely abused by the public. Chronic use of these remedies without a doctor's supervision can cause phosphate depletion, a condition that in its milder form produces muscle weakness and in more severe form leads to a vitamin D deficiency. "Unfortunately," says Dr. Roe, "some people get into the habit of taking enormous amounts of these drugs to treat gastric upset that in itself is due to their abuse of some other substance, such as alcohol, coffee, or food."

Mineral oil, an old-fashioned laxative still widely used by elderly people and in nursing homes, can hinder absorption of vitamin D. One study reported that as little as 20 milliliters (4 teaspoons) of mineral oil twice daily can interfere with absorption of vitamin D, vitamin K, and carotene, a substance the body converts to vitamin A.

Drug labels now give patients little direct information about possible reactions with foods and beverages. But under new FDA guidelines, due to become official regulations in 1979, drug manufacturers would be required to spell out known adverse reactions—with other drugs or with foods—on patient package inserts that accompany certain prescription drugs. More information on interactions also will be required on the physician labeling for drugs. Physician labeling is the information on their prescription drug products that manufacturers are required to supply to physicians. In anticipation of these regulations, some manufacturers have acted in advance to include such information with their products.

FDA also is seeking to make the labeling of over-the-counter drugs more informative. All over-the-counter drugs are being reviewed for safety, effectiveness, and labeling claims by FDA advisory panels. The recommendations of these panels may result in FDA requiring that manufacturers provide consumers with more detailed information about how certain nonprescription medicines interact with other drugs and with foods.

What can consumers do to prevent undesirable food-drug interactions? Here are a few suggestions:

- Read the labels on over-the-counter remedies and the package inserts that come with prescription drugs.
- Follow your doctor's orders about when to take drugs and what foods or beverages to avoid while taking medications.
- Don't be afraid to ask how drugs might interact with your favorite edibles, especially if you consume large amounts of certain foods and beverages. While taking drugs, be sure to tell your doctor about any unusual symptoms that follow eating particular foods.
- Eat a nutritionally well-balanced diet from a wide variety of foods. Use of a needed drug, even on a long term basis, is less likely to cause depletion of vitamins and minerals if your overall nutritional status is good.

Drug labeling and informed health professionals can be helpful to you, but your doctor and pharmacist cannot follow you to the dinner table or the snack bar. Remember that warnings about food-drug interactions are only as good as the patient's willingness to heed them.

Phyllis Lehmann is a freelance writer.

REPRINTED FROM MARCH 1978

HEW Publication No. (FDA) 80-3070

FDA CONSUMER

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
Food and Drug Administration
Office of Public Affairs

• U.S. GOVERNMENT PRINTING OFFICE: 1980—311-254/12

Painkillers: Their Uses And Dangers

FDA Consumer
REPRINTED FROM SEPTEMBER 1977

HEW Publication No. (FDA) 78-3060

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
Food and Drug Administration
Office of Public Affairs

An FDA advisory panel has looked into aspirin and other nonprescription painkillers and concluded that those little pills shouldn't be taken lightly. The panel cautioned against the use of over-the-counter analgesics for rheumatism and arthritis except under the supervision of a doctor. And it warned against the use of aspirin by people who have upset stomachs and by women in the last months of pregnancy.

by Annabel Hecht

"Take two aspirin and call me in the morning."

That "line" is always good for a laugh in a comic routine, but to the pill-taking public it is no joke. Americans swallow some 19 billion aspirin a year, making it the most widely used nonprescription drug on the market. Aspirin and other painkillers, however, are not something to be taken lightly, a panel of experts has warned, especially for self-treatment of such diseases as rheumatism or arthritis.

The panel also cautioned against the use of any product containing aspirin by people who have upset stomachs, even if the aspirin is intended to relieve a headache that occurs at the same time as the stomach distress.

The group of experts, called together by the Food and Drug Administration to look at ingredients in internal analgesics (pain relievers), is one of 17 such panels which have been studying the safety and effectiveness of drug products that can be purchased over the counter. For purposes of the review nonprescription drugs have been divided into product categories, such as antacids, laxatives, and cough-cold remedies. The internal analgesics panel is the seventh to make its recommendations to FDA on standards for the ingredients and labeling of the group of drugs it was asked to review.

FDA has issued final regulations for over-the-counter antacids and is expected to do so for laxatives before the end of the year.

The internal analgesics panel reviewed 15 ingredients to determine whether they are safe and effective as painkillers (analgesics), fever reducers (antipyretics), and inflammation reducers (antirheumatics). Seven of the ingredients contain salicylic acid and eight do not.

Both salicylate and nonsalicylate painkillers have a long history of use. For centuries the bark and leaves of the willow, poplar, spirea, and other plants were used to ease pain and cure fevers. The active ingredient that made these early remedies effective—salicylic acid—was isolated in the early 19th century. Methods for making salicylic acid in the laboratory were developed in 1874 and its potential for the treatment of rheumatic conditions and gout was realized soon after. Aspirin, by far the most widely used salicylate today, was developed in 1853 but not used medically until 1899.

Nonsalicylate painkillers derived from coal tar came into use in the 1850's. Acetanilid appeared in 1852 but it was not until 1886 that its fever-reducing properties were discovered accidentally by two Austrian physicians. A search for less poisonous drugs led to the development of acetaminophen in 1893. Oldest of all the nonsalicylate pain relievers are quinine and codeine, which date to the 17th and 19th centuries respectively.

Six of the ingredients are safe and effective as painkillers and fever reducers, the panel said. Five are salicylates—aspirin, calcium carbaspirin, choline salicylate, magnesium salicylate, and sodium salicylate. The sixth is acetaminophen, a nonsalicylate frequently used as an aspirin substitute. Analgesic products with these ingredients should be permitted to claim only that they are "for the temporary relief of occasional minor aches, pains, and headache," the panel recommended. Fever-reducing products containing these ingredients should be limited to the claim that they are "for the reduction of fever." Too many claims would be confusing, the panel said, and the term "minor pain" is sufficiently broad to cover all types of pain that can be effectively treated with these ingredients.

Iodopyrine was found by the panel to be neither safe nor effective as a painkiller or fever reducer, and four ingredients—acetanilid, codeine (codeine phosphate and codeine sulfate), phenacetin, and quinine—were judged effective but not safe for nonprescription use. The panel recommended that all five of these nonsalicylates be taken off the over-the-counter market.

There was insufficient evidence to determine whether aluminum aspirin, antipyrine, salicylamide, and salsalate (antipyrine and salicylamide are nonsalicylates) are safe and effective, the panel said. It recommended that FDA continue to permit the use of these ingredients in nonprescription pain and fever medicines for up to three years if manufacturers conduct tests to establish their safety and effectiveness. A minority of the panel felt there were enough questions about the safety of antipyrine to warrant its removal from over-the-counter drugs.

The fact that some of the ingredients studied have been used for as long as 100 years does not mean they are without side effects, the panel said in calling for strong warnings on product labels.

For instance, the panel pointed out that aspirin interferes with blood clotting and if taken in the last three months of pregnancy can prolong pregnancy and labor and cause bleeding before and after delivery. The labels on products containing aspirin should warn that they should not be taken by people who are allergic to aspirin, have asthma, or are in the last three months

of pregnancy, the panel said. Labels on chewable aspirin and aspirin-containing gum also should advise against use for seven days after tonsillectomy or oral surgery.

Because aspirin and other products containing salicylic acid can cause stomach distress, increased bleeding, and even ulcers, labels on these products should warn that they are not to be used by persons who have stomach distress, ulcers, or bleeding problems, the panel said. The label also should warn against use by persons who are taking prescription drugs for anticoagulation (thinning the blood), diabetes, gout, or arthritis except under the supervision of a physician.

Fortunately, salicylates have a built-in early warning system. Overdosing will cause a ringing in the ears. Thus the panel recommended that the label caution consumers to stop taking the drug if this ringing occurs.

While acetaminophen is free of most of the side effects caused by salicylic acid, an overdose can result in serious liver damage. The panel called for labels on acetaminophen products to contain this warning: "Do not exceed recommended dosage because severe liver damage may occur."

No painkiller should be taken for longer than 10 days by adults or 5 days by children, the panel said, and the time limit for self-medication with fever reducers should be 3 days.

Nonprescription analgesics often are used to relieve joint pains and aches due to diseases such as arthritis and rheumatism. The five salicylates deemed safe and effective as painkillers also were considered by the panel as "acceptable" for use in reducing inflammation. But although these drugs can reduce inflammation, the panel expressed concern about their use for this purpose without medical supervision. The recommended nonprescription dose of these drugs may relieve the pain of arthritis or rheumatism but it may be insufficient to treat the disease that causes the inflammation. To reduce inflammation, the panel said, in most cases larger doses of these drugs are needed for long periods of time, and such doses should be used only under a doctor's supervision.

The panel raised serious questions about the promotion of over-the-counter analgesics for rheumatic diseases. The labeling and advertising now used can mislead consumers into thinking that these are minor ailments that can be self-diagnosed, the panel contended. Pain is the only symptom mentioned, the panel noted, and the consumer is never told that improperly diagnosed and treated rheumatic diseases can lead to crippling and even permanent disability.

Analgesic advertisements which suggest that arthritis is a minor disease or that alleviation of pain with "extra strength aspirin" will control the disease could delay proper diagnosis and treatment, the panel said. To prevent this, it recommended that nonprescription analgesics be prohibited from making any claims relating to the treatment of rheumatic diseases. Terms such as "arthritis," "rheumatism," "minor pain of arthritis or rheumatism," "arthritis strength," and "arthritis pain formula" should be removed from nonprescription products, including brand names, the panel said. Labeling for salicylate painkillers should indicate that the product is to be used to treat arthritis only under the supervision of a physician.

Acetaminophen, the only nonsalicylate ingredient rated safe and effective by the panel for the relief of pain, does not reduce inflammation and was rated not safe and effective for this purpose. The panel said acetaminophen should be labeled with the warning: "Do not take this product for the treatment of arthritis except under the advice and supervision of a physician."

The panel also found acetanilid, codeine (codeine phosphate and codeine sulfate), iodopyrine, phenacetin, and quinine not safe and effective as inflammation reducers and urged that their use for that purpose in nonprescription drugs be prohibited. Salicylamide was found to be ineffective in reducing inflammation. The panel said there was not enough information available to determine whether aluminum aspirin, antipyrine, and salsalate are safe and effective for reducing inflammation. These drugs should be permitted to remain on the market for the treatment of inflammation for up to three years if their manufacturers conduct tests to establish their safety and effectiveness, the panel said. But, as with other nonprescription inflammation reducers, the panel recommended that these drugs be used only under the guidance of a physician.

The panel said it is important to establish a safe, standard dosage for aspirin and the other salicylates because overdose can lead to salicylate poisoning and even death. Consumers who follow the rule of thumb—"take two aspirin"—run the risk of serious toxic effects if they take a product with a larger amount of aspirin per tablet than is found in most nonprescription drugs.

The panel strongly recommended establishment of a standard tablet containing 325 milligrams (mg), which is the same as 5 grains, for the three most commonly used pain and fever medicines: aspirin, acetaminophen, and sodium salicylate. Tablets containing different dosage units should be labeled to show that they are more or less than the standard, the panel said.

The recommended adult oral dosage schedule for aspirin should be 325 milligrams (5 grains) to 650 milligrams (10 grains) every 4 hours not to exceed 4,000 milligrams (60 grains) in 24 hours. The same schedule would apply to acetaminophen and sodium salicylate. The panel also proposed a sched-

ule for nonstandard tablets which would limit the total daily dosage to 4,000 milligrams or less (see Table I).

The panel found that there is no single recognized recommended aspirin dosage schedule for children. The doses recommended on the labels of products now on the market are too low, according to the panel. This could cause overdosing, one drug manufacturer told the panel, because if the drug isn't having the desired effect a parent might give a child too much at one time or repeat dosing before the recommended time interval.

The panel recommended an aspirin dosage schedule for children which starts out with an adequate dose and repeats it every four hours (see Table II). The panel also recommended that the standard tablet for children's aspirin be 80 milligrams (1.23 grains). This would mean that one-half of a standard adult tablet would be equal to two standard children's tablets. These recommendations also apply to standard children's doses of other pain and fever drugs. There should be no recommended children's dosage for nonstandard tablets, the panel said.

No more than two active analgesic ingredients should be permitted in a nonprescription pain or fever drug, the panel said. It raised no objection to products that combine a nonsalicylate painkiller with an antacid for "temporary relief of occasional minor aches, pains, and headache, and for the reduction of fever, and for acid indigestion."

But the panel called "irrational" the combination of aspirin or other salicylates with an antacid for the treatment of heartburn, sour stomach, or acid indigestion. Aspirin in any form can cause bleeding and stomach distress, the panel said, including highly buffered aspirin that is intended to be dissolved in water and which is claimed to be safe for use by people who have an upset stomach along with a headache.

There is evidence that highly buffered solutions will reduce the side effects of aspirin, but they will not eliminate them, the panel contended. In fact, such products may increase the risk of bleeding because they deliver more pure aspirin to the system than regular aspirin products. The group expressed concern that alcohol and stress, factors which most frequently "prime" the gastrointestinal tract for massive bleeding, are also the factors which most frequently cause upset stomach and headache at the same time.

To prevent the public from being misled into thinking that highly buffered aspirin is the safest aspirin product to take for both headache and upset stomach, the panel recommended that all products containing aspirin be required to carry the following label warning: "Do not take this product if you have stomach distress, ulcers, or bleeding problems except under the advice and supervision of a physician."

The panel did not object to the use of buffered aspirin. It said studies have shown that the addition of alkaline buffers makes aspirin dissolve more quickly, speeding up its absorption into the system. This reduces but does not eliminate the irritating effects of aspirin on the stomach. The panel expressed concern about the labeling of such products, however, since there have been no well-controlled clinical studies to prove that buffered aspirin goes to work faster or is more effective than plain aspirin. In addition, not all brands of buffered aspirin dissolve at the same rate and not all dissolve faster than plain aspirin.

The panel recommended that statements suggesting that buffered aspirin is superior to plain aspirin be limited to: "Faster to the bloodstream than plain aspirin," and "Provides ingredients that may prevent the stomach distress that plain aspirin occassionally causes but should not be taken by certain individuals with stomach disorders as cautioned elsewhere on the label." The use of even these claims should be halted after three years unless the manufacturers of buffered aspirin can prove they are valid, the panel said, and any other claims of fast action or gentleness to the stomach should be removed from buffered aspirin labels.

The panel said aspirin should not be combined with drugs used for the treatment of asthma (bronchodilators), and no pain-killing ingredient should be combined with laxatives or vitamins. Combining painkillers with nighttime sleep-aids should be permitted if the manufacturers of such products can define a "target population" in need of such a combination, the panel said. It recommended that if such products are permitted they be labeled for the temporary relief of minor aches and pains, reduction of fever, and "for the relief of occasional sleeplessness."

Reports of all the FDA panels on over-the-counter drugs are advisory in nature. FDA publishes the reports to give interested persons an opportunity to comment on specific recommendations. The report of the Panel on Review of Internal Analgesics Including Antirheumatic Drugs was published in the July 8 FEDERAL REGISTER. Comments may be sent to the FDA Hearing Clerk, 5600 Fishers Lane, Rockville, Md. 20857 until November 5.

These comments will be carefully considered by FDA in developing final regulations on the acceptable ingredients, dosage, and labeling for nonprescription internal analgesic products. Although it may be many months before final regulations are published, consumers may see changes in some familiar products as manufacturers alter formulations or labeling in anticipation of new regulations.

Annabel Hecht is a staff writer with FDA's Office of Public Affairs.

Table I

Recommended Adult Dosage Schedule for Nonstandard Aspirin Tablets

Amount of Aspirin Contained in One Tablet	Number of Tablets That Can Be Taken Initially	Number and Timing of Tablets That Can Be Taken After Initial Dose	Total Number of Tablets That Can Be Taken in 24 Hours
400 milligrams (6.15 grains)	1 to 2	1 after 3 hours	9
421 milligrams (6.48 grains)	1 to 2	1 after 3 hours	9
485 milligrams (7.46 grains)	1 to 2	1 after 4 hours or 2 after 6 hours	8
500 milligrams (7.69 grains)	1 to 2	1 after 3 hours or 2 after 6 hours	8
650 milligrams (10 grains)	1	1 after 4 hours	6

Table II

Recommended Aspirin Dosage Schedule for Children

Age	Children's Tablets [1] (80 milligrams—1.23 grains) Number of Tablets That Can Be Taken Every 4 Hours	Standard Adult Tablets [1] (325 milligrams—5 grains) Number of Tablets That Can Be Taken Every 4 Hours
Under 2 [2]		
2 to under 4	2 (160 milligrams)	1/2 (162.5 milligrams)
4 to under 6	3 (240 milligrams)	3/4 (243.8 milligrams)
6 to under 9	4 (320 milligrams)	1 (325 milligrams)
9 to under 11	5 (400 milligrams)	1 1/4 (406.3 milligrams)
11 to under 12	6 (480 milligrams)	1 1/2 (487.5 milligrams)

[1] Not to exceed five single dosages in 24 hours or to be used for more than five days except under the advice and supervision of a physician.

[2] No recommended dosage except under the advice and supervision of a physician.

FDA Consumer
REPRINTED FROM MARCH 1976

HEW Publication No. (FDA) 76-3020

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
Food and Drug Administration
Office of Public Affairs

Mixing Medicines? Have A Care!

When different drugs meet inside the human body, they can touch off some unusual reactions. Drugs sometimes are prescribed so they will interact and produce a desired result. But mixing drugs without a physician's advice can produce unexpected and dangerous side effects.

by Timothy J. Larkin

Although not the definition cited by scientists, chemistry could be defined as the science of combining substances so that the whole is usually surprisingly different from the sum of its parts. Take a positive ion of the soft metal sodium which can burn the skin or explode when mixed with water. Combine this hazardous substance with a negative ion of the poisonous, greenish-yellow gas chlorine. The result is not an even more dangerous chemical, but something quite different, the universal seasoning, the white currency with which Roman legionnaires were paid—salt.

Perhaps even more extraordinary is the end result of combining two atoms of hydrogen gas and one of oxygen. The product, water, possesses properties that would have been impossible to predict from the qualities of its constituents.

If simple chemical combinations can produce such seemingly unrelated and surprising offspring, it should not be surprising that when two or more different drugs meet inside the human body some unusual results may occur.

The results of some drug interactions are unimportant. Others, however, can mean the difference between successful and unsuccessful treatment; can produce a false reading of a laboratory test; can cause unexpected and possibly serious—even fatal—side effects; or can set off puzzling or misleading symptoms.

Although the FDA requires that the manufacturer of a new drug prove its safety and effectiveness, the drug producer does not routinely carry out, and is not required by law to carry out, tests for safety and effectiveness that involve simultaneous use of several drugs. One reason is that the whole problem of drug interactions is still new and incompletely understood. Another is that it is an endlessly complicated business.

Complex, partially understood, but nonetheless important. Fortunately, largely due to the reporting of such interactions by physicians and pharmacists, a number of important facts have become known. As factual knowledge about potentially significant drug interactions emerges, the FDA requires that such information be reflected in the label that accompanies nonprescription (over-the-counter) medicines and the labeling information available to pharmacists and physicians for prescription drugs. FDA also publishes a widely distributed monthly collection of data about interactions and other important effects of drugs.

Drugs interact in a number of ways. One drug may make another drug act faster or slower, or more powerfully or less powerfully than it normally would. One drug may change the effect another drug has on the body.

A fairly common way one drug acts on another is by affecting the way it is absorbed, distributed, or broken down (metabolized) by the body. For example, let's assume that you are afflicted with a circulatory problem due to clotting of blood in an artery or vein. Your physician may prescribe an anticoagulant medicine — a medicine that "thins" the blood and thus helps dissolve the clot. If, at the same time, you are taking an antacid, even a nonprescription antacid, the anticoagulant may be absorbed at a slower rate than required to do its job properly.

Alcohol and anticoagulants can interact in two ways, both serious. Chronic alcohol abuse will speed up the rate by which the liver metabolizes or breaks down the anticoagulant, reducing its effect. But drinking a great deal of alcohol in a short period can slow down the metabolism. This can magnify the impact of the anticoagulant to the point where the blood becomes so thin it may be difficult to halt bleeding caused by an injury or from an ulcer aggravated by the alcohol.

It should be noted that a number of popular nonprescription cough and cold medicines contain up to 15 percent alcohol, and that alcohol interacts not only with anticoagulants but also with a number of other medicines. For example, if a person taking nitroglycerin for angina pectoris, a painful heart ailment, is also drinking alcoholic beverages, the result may be hypotension—low blood pressure—serious enough to cause a failure of the blood circulatory system.

In addition to interfering with absorption, distribution, and metabolism, one drug can also either inhibit or hasten the excretion of another, and thus either exaggerate or reduce the effect of the drug. One common way this occurs is through the taking of nonprescription drugs that change the pH or acid level of the urine. Prescription medicines are formulated on the basis of a normal level of acid (pH) in the urine. But certain nonprescription drugs (such as those containing ammonium chloride, sodium bicarbo-

nate, or citrates) change the pH, and this can interfere with the otherwise beneficial impact of the prescription medicine.

For a somewhat more complicated example, should you be taking the oral antidiabetic drug acetohexamide and also take phenylbutazone, which is often prescribed to relieve the pain of arthritis or gout, a breakdown product of the antidiabetic drug will not be excreted at sufficient speed through the kidneys. The result can be a serious and prolonged deficiency of blood sugar.

When a number of drugs are being taken, consideration must be given to the effect of adding one drug to another—their cumulative impact. This so-called additive reaction is especially important if the drugs are similar in their general effect.

There are some drugs which, when combined, produce reactions that go beyond what one might assume would result from adding the effect of one to the other. With such drugs, the end result is greater than the sum of the two parts. This type of action, in which the effects from two drugs are not simply added to each other but are multiplied, is called potentiation.

Potentiation can greatly accelerate the helpful effect of a drug, as when the antibiotic trimethoprin may be used to enhance the activity of the antibiotic sulfamethoxazole in combating certain infections. But potentiation also can be one of the most dangerous forms of drug interaction, and a number of deaths of otherwise healthy persons have been reported that resulted from potentiation, particularly through mixing alcohol with sleeping aids, pain relievers, or tranquilizers.

Even commonly used nonprescription medicines can have potentiating effects. Aspirin greatly increases the blood-thinning effect of oral anticoagulants. Therefore, a person who is taking such medication may risk hemorrhage if he or she uses aspirin to alleviate a headache.

Many nonprescription cold remedies contain antihistamines which can produce potentiating effects when taken in conjunction with alcohol or with a wide variety of prescription and other nonprescription drugs, particularly those that act as central nervous system depressants, including anesthetics, barbiturates, hypnotics, sedatives, and analgesics.

One important kind of drug reaction does not involve one drug interacting with another in the body to produce an unwanted side effect, but rather a drug affecting the body chemistry in a way that skews or confuses the results of diagnostic tests. Ordinary nonprescription drugs can have this skewing effect and so can vitamins. For example, laboratory tests to determine a patient's calcium or bone metabolism can be affected by excess use of laxatives. Vitamins A, D, and K, as well as such common over-the-counter drugs as aspirin, can produce false positive or negative readings in a great number of important tests used by physicians to diagnose illness. And large doses of vitamin C can produce false negative urinary glucose tests which can, therefore, mask a diabetes condition.

How can you protect yourself against a harmful drug interaction? Here are some suggestions:

- When your physician prescribes a drug for you make sure he knows what other drugs you are taking. All of them. Remember that the words "drug" and "medicine" mean the same thing, and that alcohol is a drug. Headache remedies, cold medicines, laxatives, and other nonprescription medicines are drugs. When your physician asks, "Are you taking any other medicines?" no drug is too unimportant to mention. The drugs cited in this article are among the most widely prescribed medicines, but they represent only a few of the hundreds of drugs that involve significant interactions.
- Don't start taking a second drug unless your physician knows about it. It's also a good idea to tell your pharmacist when he fills a prescription what other drugs you are taking. He may wish to set up a personal record so that he can tell at a glance if you may be exposed to a drug interaction.
- Don't take a drug prescribed for someone else because it is "good for stomach pain," or whatever it is that is troubling you. The drug in that prescription may interact with something else you are taking, or it may not be suitable for you or your ailment.
- Read the label. Over-the-counter medicines are required by FDA to contain information about significant drug interactions.
- Remember that drugs have three names. There is the chemical name, which is usually not given on the label. There is what is called the generic name, which is the official, established name for a drug; and there is the proprietary name or the trade-marked brand name for that drug.

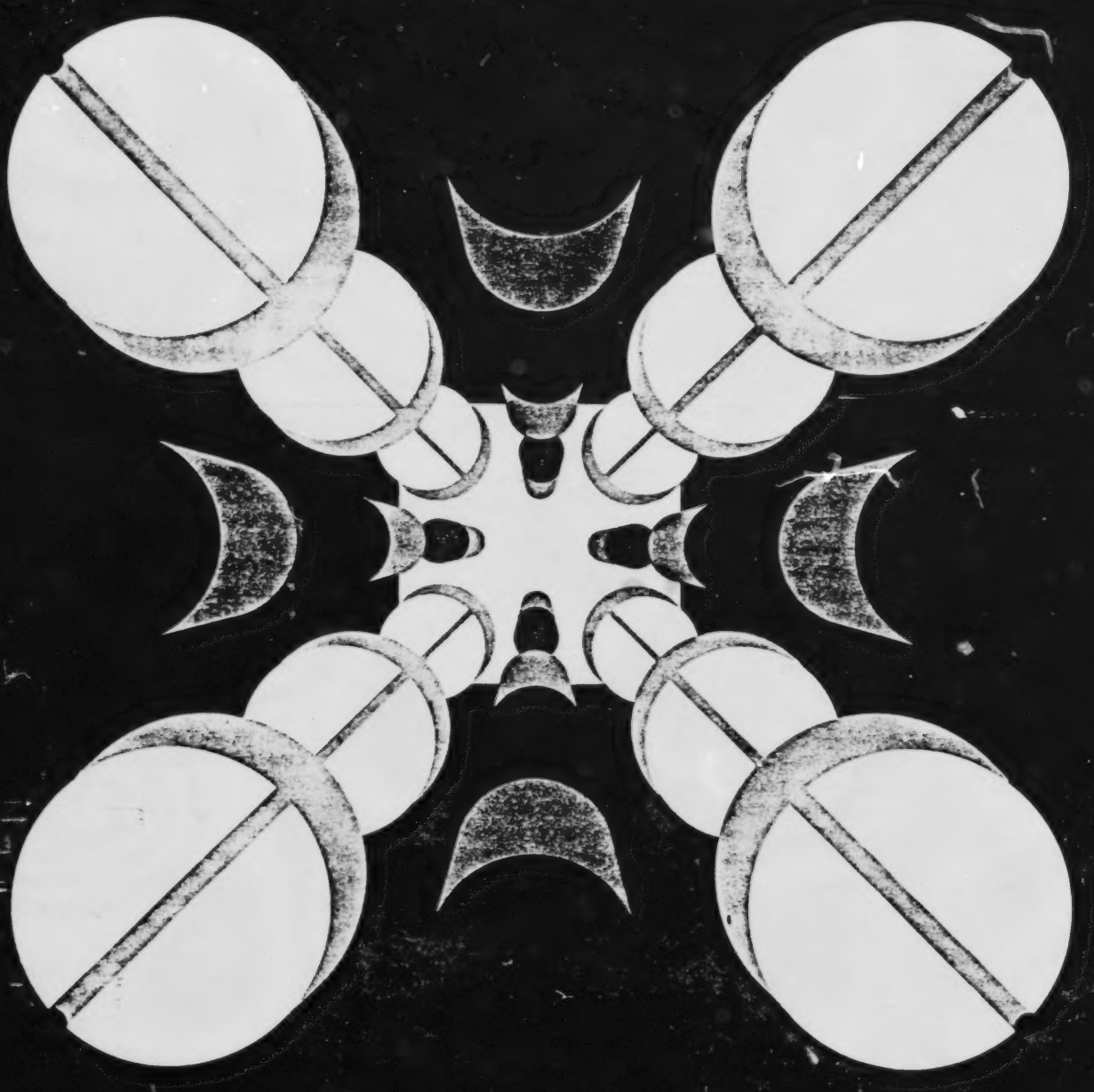
It is important to remember this because the warnings printed on labels give the generic name. Thus, a number of nonprescription medicines such as the antacids warn against taking the medicine with tetracycline, which is the generic name of an antibiotic. However, Achromycin, Azotrex, Kesso-Tetra Syrup, Sumycin, Panmycin, Tetrastatin, and over a dozen others are proprietary names for tetracycline. So, unless you know the generic name as well as the proprietary name, you may be exposing yourself to a drug interaction. To avoid this, ask your physician or pharmacist to tell you the generic name of any prescription drugs you may be taking.

- It is also worth remembering that numerous drugs contain more than one ingredient. Empirin, a medicine widely used for relief of simple headache and other discomforts, contains aspirin as well as phenacetin and caffeine.
- Finally, since knowledge about drug interactions is by no means complete, and individuals differ in their reactions to drugs, you may possibly experience a reaction to a mixture of drugs that is unknown, not only to your physician and pharmacist, but to the medical profession generally. So, if you are taking more than one drug and you become ill, by all means report it to your physician or pharmacist.

Timothy Larkin is a special assistant to the Commissioner of Food and Drugs.

Generic Drugs:

How Good Are They?



by Annabel Hecht

All drugs, whether they are sold under their brand names or their generic names, must meet the same FDA standards for safety, strength, purity, and effectiveness. And all drug manufacturers, big or small, are subject to FDA inspection and must follow the Agency's Current Good Manufacturing Practice Regulations. That is why FDA believes there is no significant difference in quality between generic and brand name drugs.

Are generic drugs as good as brand name products?

The answer to that frequently asked question is, for the most part, "yes," according to the Food and Drug Administration. As FDA Commissioner Donald Kennedy has said, "There simply is no evidence to support the notion of serious quality differences between generic and brand name drugs."

The differences are largely semantic. All drugs have a generic name, also called the "official" or "nonproprietary" name. A generic name is assigned to a drug when it appears that it has some therapeutic usefulness. Newly developed drugs also are given brand or trade names. Unlike generic names which usually are contractions of a complex chemical name, brand names generally are short, easy to remember, and often devised to suggest the pharmacological action of the drug.

It is the brand name that is used to advertise a drug to the medical profession, although the generic name must appear in advertising and labeling in letters at least half as big as that of the brand name. Aspirin, for instance, is the generic name for the leading nonprescription painkiller; Bayer and St. Joseph's are brand names for different manufacturers' aspirin. Whether you buy a bottle of "house brand" aspirin at a discount drugstore or a nationally advertised brand, there will be no difference in the pain-killing quality of the products because any drug that claims to be aspirin must meet the official FDA standards for that drug.

The same principle applies to prescription drugs.

Tetracycline is a widely used prescription antibiotic. A physician may write a prescription for this drug by its generic name, or may prescribe it under the brand names Achromycin, Sumycin, or Tetracyn. No matter what name is used, each drug must meet the same standards for tetracycline. (Antibiotics have an extra measure of assurance because every batch of antibiotics must be tested and certified by FDA before it can be sold.)

It is a popular misconception that brand name drugs are produced only by large, well-known firms, while generics are made by small, unknown companies. A small drug company can put a brand name on its product just as a large company can market a drug under its generic name. And many large drug firms distribute, under their brand names, products that have been manufactured, packaged, and labeled by firms that make generic drugs. Some manufacturers may make a drug and sell it under both a trade name and its generic name. In other instances large firms may make the final dosage form from drugs purchased in bulk from other companies.

As an example of the complexities of drug marketing, ampicillin, a widely used antibiotic available under 224 product labels, is produced by only 24 formulators, and 219 conjugated estrogen products are produced by 45 manufacturers.

Since the name of the actual manufacturer of a drug does not have to appear on the product label (except in a few States), neither consumers nor pharmacists may be aware that a drug carrying the brand name of one company actually was made by another firm.

Not only must each drug meet FDA requirements, so must each drug plant. All firms—large and small—must register with FDA; all are subject to periodic inspection, and all must follow FDA Good Manufacturing Practice Regulations (GMP's) that touch on every aspect of making drugs, from building maintenance to quality control. These regulations apply to all producers and are intended to assure that all drugs meet the same standards of safety, strength, purity, and effectiveness. These requirements, in fact, were built into the 1962 amendments to the food and drug laws for the very purpose of encouraging physicians to make wider use of generic drugs in order to lower the cost of medical care, according to the co-sponsor of the legislation, the late Senator Estes Kefauver.

Other FDA standards provide further assurance of drug equivalence.

Before a new drug can be put on the market, the manufacturer must submit an application to FDA. It must include the results of tests carried out by the manufacturer in several phases—in the laboratory, in animals, and finally in human volunteers—which demonstrate that the drug is safe and effective for its intended use. If the application is approved the manufacturer may market the drug. If the manufacturer has patented the product, that manufacturer has the sole right to sell the drug until the patent expires. In some instances a patent holder may give other firms the right—usually in return for payment of a royalty—to make and sell a patented drug. Drug patents run 17 years. If there is no patent or the patent has expired, other firms may manufacture and sell the drug, either under its generic name or under different brand names.

These firms, however, must file an application with FDA giving details about their plants and personnel, and how they will make the drug. FDA inspectors visit these plants to determine whether they have the capability to produce the drug. Samples of the product are tested in an FDA laboratory to make certain they meet the official standards. While these manufacturers usually do not have to go

through the full range of tests required of the firm that submitted the original application to market the drug, they may be required to carry out some studies to assure FDA that their products will be up to standards established for the drug.

Another assurance of drug quality stems from FDA's monitoring programs. FDA periodically collects samples of all drug products, both generic and brand name, from manufacturers and from the marketplace to test them for purity and strength. FDA has two specially equipped laboratories for this testing. The National Center for Drug Analysis in St. Louis, Missouri, does the bulk of this work, while about 10 percent is carried out by the Winchester Engineering and Analytical Center near Boston. Automated equipment in these labs permits rapid analysis of many drug samples at the same time. When trouble is found or suspected, the drug company is notified immediately. Faulty products are removed from the market.

Batch testing and certification is required by law for insulin and for biological products such as vaccines and serums, as well as for all antibiotics. When FDA discovers particular problems with a drug, as it did for the heart drug digoxin a few years ago, it may require that each batch of that drug be tested before it can be released for sale.

Testifying before a Senate subcommittee, FDA Commissioner Kennedy noted that as far as quality is concerned FDA's analysis of drug samples revealed "no evidence of widespread differences between the products of large and small firms, or between brand name and generic name products." In regard to recalls of defective products, Kennedy said, "We are unable to conclude that there is any clear difference between large and small firms based on the recall record."

As better methods have been developed to determine how fast a drug dissolves, a new dimension has been

FDA Endorses New York Equivalent Drug List

The Food and Drug Administration (FDA) has advised New York that the State's newly published drug list is an accurate guide to prescription drugs considered by FDA to be safe, effective, and equivalent in therapeutic performance.

FDA said that the New York drug list may be useful to other States which, like New York, allow pharmacists to substitute less expensive "generic" drugs for equivalent higher priced brand name products.

The New York drug list was prepared and issued as part of a new State program to reduce prescription drug costs without sacrificing quality.

Under the New York law, beginning April 1 physicians may, after notifying the patient, instruct the pharmacist to fill a prescription with a less expensive product provided it is listed in the State's list of drugs.

In explaining the significance of FDA's action, Commissioner of Food and Drugs Donald Kennedy said: "FDA concurrence in the New York list reflects the Agency's view that there is no consistent difference in quality between drug products sold by large and small firms or between drugs sold under a brand name or 'generic' name. We have a single standard for drugs in this country."

The Commissioner continued: "FDA plays no formal role in how prescriptions are written or filled. State laws govern whether pharmacists can use their professional judgment in substituting a less expensive product when a doctor writes a prescription for a more expensive one.

"The list compiled by New York State contains drug products we believe doctors can prescribe and pharmacists can dispense with confidence.

"States that permit substitution and want some assurance of therapeutic equivalence can use this New York State publication with knowledge that FDA has approved all the products on the list and the manufacturers listed have FDA approval to make them."

The New York drug list was compiled with FDA assistance after the State legislature enacted a law that requires all prescription forms used after April 1, 1978, to contain two signature lines for the physician. Beneath one line the words "substitution permissible" are imprinted; beneath the other are the words "dispense as written."

The doctor may sign either line. If the doctor decides that substitution is permitted, the pharmacists must substitute a less expensive product, provided it is on the State list.

As an example of how a drug is listed, tetracycline hydrochloride, a frequently prescribed antibiotic, is listed as being made by 26 manufacturers. Ten of those manufacturers are listed as selling the antibiotic under a brand name such as Achromycin, Panmycin, or Tetracyn, while the remaining 16 sell it under its generic name, tetracycline hydrochloride.

A drug product will remain in the official listing as long as there are no unresolved problems about its equivalence.

Commissioner Kennedy's endorsement of the New York State list was contained in a letter to State Health Commissioner Robert P. Whelan.

added to FDA's testing program. Under new FDA regulations, manufacturers seeking Agency approval to market a new drug product or make changes in an existing product must conduct tests in human volunteers to determine how much of the active drug ingredient is absorbed by the body, how fast it is absorbed, and the length of time it circulates in the blood. This becomes the standard for that drug and other manufacturers who want to market the same drug are required to meet the same standard.

Certain drugs have shown inconsistencies in their absorption rate or in how long they remain in the bloodstream. For example, tests may have shown that different batches of the same drug made by the same manufacturer have differed in their absorption rate. In other instances, a drug made by one manufacturer may have shown a different absorption rate than the same drug made by another manufacturer. When this occurs, the drug is said to have "bioequivalence" problems, which means that there has been difficulty in assuring that different batches of the drug will always behave in the body in the same way.

The new FDA regulations spell out special procedures for drugs with known or suspected bioequivalence problems. Manufacturers wanting to market such drugs will have to conduct certain additional tests in humans and animals as well as in the laboratory. Batch-by-batch certification by FDA could be a part of the requirement if the Agency considers it necessary. After the requirements have been satisfied, FDA will continue to check on these drugs from time to time to make certain they are up to standard.

While most drugs do not pose "bioequivalence" problems, about 30 have been identified which will require additional tests for bioequivalence.

FDA's program to assure that generic drugs are as good as brand name products should be of more than passing interest to consumers, for it concerns their wallets as well as their health. Because generics generally are cheaper than their brand name equivalents, economists long have maintained that one way to help hold down the rising cost of medical care is to encourage physicians to prescribe drugs by their generic names, and to encourage pharmacists to fill prescriptions with the lowest-cost version of the prescribed drug.

There has been a growing movement among the States to overturn laws which forbid pharmacists from dispensing any version of a drug product other than that specifically prescribed by the doctor. Under such laws, if a doctor prescribes a certain brand of tetracycline a pharmacist cannot substitute generic tetracycline or even another brand, although they may cost less and are the chemical "twin" of the prescribed brand. Only twenty-one States still have these so-called anti-substitution laws. Some States that have relaxed them now permit the pharmacist to choose a substitute product unless the prescriber forbids it, while other States require a prescription form with two signature lines on which the prescriber must indicate approval or disapproval of substitution.

Even without changes in the law, generic prescribing is on the rise. A national audit of prescriptions filled in retail pharmacies showed that 86.5 million generic prescriptions were filled in 1976, nearly 12 percent of the total new prescriptions for that year. Ten years earlier generic prescriptions accounted for only 6.4 percent of the total. Another survey predicts that by 1985 the number of generic prescriptions will triple as drug patents expire. At present, of the 200 most frequently prescribed drugs, about 60 to 70 are available generically, but of these only 15 are prescribed with any frequency.

Antibiotics top the list of the 20 leading generic drugs. Prescriptions for the six most popular generic antibiotics totaled well over 46 million in 1976, representing 54 percent of all generic prescriptions.

In the face of FDA's assurances that there are no differences between generic and brand name drugs, consumers might ask why physicians don't write more generic prescriptions. There is no single answer to that question. Some physicians may feel more confidence in the products of familiar drug companies. Others may not be aware of the difference in price between a brand name drug and its generic equivalent, or they may not know that a generic version of a particular drug is available. Patients who are concerned about their health care dollars may wish to ask their physicians to prescribe and their pharmacists to dispense generic drugs when they are available.

Another factor that plays an important role in influencing physicians' prescribing practices is the promotional activities of drug manufacturers. One form of this promotion is advertising in medical journals. Another is personal visits from representatives, called "detail men," who talk up their company's products and leave samples and attractive literature with the physicians they call on. A third channel of promotion is the PHYSICIANS' DESK REFERENCE, a publication made available without charge to physicians and some pharmacists. Drug companies pay to have essential information about their products included in this valuable reference work. Those that do not pay do not have their products listed.

After years of this kind of promotion, it is little wonder that physicians tend to prescribe a drug by its brand name purely out of habit, even when a generic version is available.

As the public and the medical, pharmacy, and other health professions gain more understanding of the quality assurance programs enforced by FDA, generic prescribing and purchasing is likely to increase. The result should be lower cost, but equal quality health care.

Annabel Hecht is a staff writer with FDA's Office of Public Affairs.

☆U.S. GOVERNMENT PRINTING OFFICE: 1978-260-948/31

FDA Consumer
REPRINTED FROM FEBRUARY 1978

HEW Publication No. (FDA) 78-3068

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
Food and Drug Administration
Office of Public Affairs

CENTER PRESENTATION HANDOUTS

It's Dangerous to Mix Alcohol and Drugs

In recent years, hundreds of new drugs have been introduced for inducing sleep and for tranquilization, sedation, relief of pain, motion sickness, head colds, and allergy symptoms. Too numerous to name, they include narcotics, barbiturates and other hypnotic-sedative drugs, tranquilizers, and antihistamines.

Alcohol is a drug which can produce feelings of well-being, sedation, intoxication, and unconsciousness. Since alcohol works on the same brain areas as some of these other drugs, it can multiply the usual responses normally expected from either the drug or the alcohol alone, if they are taken fairly close to one another. For example, alcohol and barbiturates in combination increase each other's effects on the central nervous system and can be particularly dangerous. Alcohol in combination with any drug that has a depressant effect on the central nervous system likewise represents a special hazard to health and safety -- sometimes to life itself. Some understanding of metabolism, i.e., the way our bodies chemically process the things we eat, drink, or take, is necessary to explain this reaction.

If drugs were not metabolized within the body their effect would continue for the remainder of a person's life. In the metabolic process, drugs are transformed into other substances, which are eventually eliminated through normal bodily functions. The more rapid the rate of metabolism, the lower the impact of the drug. When drugs are forced to compete with alcohol for processing by the body, alcohol is metabolized first, while the other drug remains active in the blood for an extended period of time. As a result, the drug's effect on the body is exaggerated, since its metabolism is slowed down due to the body's tendency to take care of the alcohol first. When added to the normal depressant consequence of alcohol, further depression of the nervous system which regulates vital body functions occurs. This is a serious condition that can result in death.

There is another danger, which can also lead to serious problems in persons who habitually drink large amounts of alcohol. As a result of excessive drinking, during periods of sobriety, barbiturates or sedatives will have less effect, since these drugs are more rapidly metabolized. It is therefore not uncommon for heavy drinkers to take ever larger doses of drugs, because the usual quantities taken by non-drinkers or moderate drinkers will have little effect. The results of taking the large doses and then drinking can place these persons in even greater jeopardy and can be fatal.

Think Before You Drink

If you want to take a drink when you are also taking medication, three actions may save you from a serious illness or accident, or may even save your life:

- Read the warnings on non-prescription drug labels or those on your prescription container
- Ask your doctor about possible alcohol/drug interactions
- Check with your pharmacist if you have any questions about your medication, especially those you can buy without a doctor's prescription

THREE STEPS TO WISE MEDICATION USE

STEP 1

TALK TO YOUR DOCTOR

The wise patient will tell the doctor about *all* medications he or she is already taking, because certain drugs should not be taken together. Be sure you understand the doctor's instructions before you leave -- get the instructions in writing, if necessary.

STEP 2

TALK TO YOUR PHARMACIST

The wise purchaser discusses the medication with the druggist. If you ask, the pharmacist can give you easier-to-read labels, easy-open caps, and information about money-saving generic drugs.

STEP 3

TAKE YOUR MEDICINES CAREFULLY

The wise consumer stores medicines properly and has a system for keeping track of how often each one is used. Discard old, outdated medicines. Don't suddenly stop taking a medicine without checking with your doctor.

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
Alcohol, Drug Abuse, and Mental Health Administration

What Could Happen if You Drink While Taking Any of These Drugs

The chart below lists classes of drugs which have been reported to interact with alcohol. Some of the dangers that may result from combining alcohol with the other listed drugs are described. If you asked for information on a specific drug, a check-mark has been placed in the box preceding the class of drug which best describes the one for which you requested information. It must be emphasized that this chart, or any other like it, only represents the smallest part of the whole alcohol/drug interaction picture. It is not meant to replace the advice of your family doctor or your pharmacist.

☐ ANALGESICS, NARCOTIC
(Demerol, Darvon, Dilaudid, etc.)

When used alone, both alcohol and narcotic drugs cause a reduction in the function of the central nervous system. When used together, this effect is even greater, and may lead to loss of effective breathing function (respiratory arrest). Death may occur.

☐ ANALGESICS, NON-NARCOTIC
(Aspirin, APC, Pabalate, etc.)

Even when used alone, some non-prescription pain relievers can cause bleeding in the stomach and intestines. Alcohol also irritates the stomach and can aggravate the bleeding, especially in ulcer patients.

☐ ANTIALCOHOL PREPARATIONS
(Antabuse, Calcium Carbamide)

Use of alcohol with medications prescribed to help alcoholic patients keep from drinking results in nausea, vomiting, headache, high blood pressure and possible erratic heart beat, and can result in death.

☐ ANTICOAGULANTS
(Panwarfin, Dicumarol, Sintrom, etc.)

Alcohol can increase the ability of these drugs to stop blood clotting, which in turn can lead to life-threatening or fatal hemorrhages.

☐ ANTICONVULSANTS
(Dilantin, Diphenyl, EKKO, etc.)

Drinking may lessen the ability of this drug to stop convulsions in a person.

☐ ANTIDEPRESSANTS
(Tofranil, Pertofrane, Triavil, etc.)

Alcohol may cause an additional reduction in central nervous system functioning and lessen a person's ability to operate normally. Certain antidepressants in combination with red wines like Chianti may cause a high blood pressure crisis.

☐ ANTIDIABETIC AGENTS/HYPOGLYCEMICS
(Insulin, Dymelor, Orinase, etc.)

Because of the possible severe reactions to combining alcohol and insulin or the oral antidiabetic agents, and because alcohol interacts unpredictably with them, patients taking any of these medications should avoid alcohol.

☐ ANTIHISTAMINES
(most cold remedies, Actifed, Coricidin, etc.)

Taking alcohol with this class of drugs increases their calming effect and a person can feel quite drowsy, making driving and other activities which require alertness more hazardous.

☐ ANTIHYPERTENSIVE AGENTS
(Serpasil, Aldomet, Esidrix, etc.)

Alcohol may increase the blood pressure lowering capability of some of these drugs, causing dizziness when a person gets up. Some agents will also cause a reduction in the function of the central nervous system.

☐ ANTIINFECTIVE AGENTS/ANTIBIOTICS
(Flagyl, Chloromycetin, Seromycin, etc.)

In combination with alcohol, some may cause nausea, vomiting, and headache, and possibly convulsions, especially those taken for urinary tract infections.

☐ CENTRAL NERVOUS SYSTEM STIMULANTS
(most diet pills, Dexedrine, Caffeine, Ritalin, etc.)

Because the stimulant effect of this class of drugs may reverse the depressant effect of the alcohol on the central nervous system, these drugs can give a false sense of security. They do not help intoxicated persons gain control of their movements.

☐ DIURETICS
(Diuril, Lasix, Hydromox, etc.)

Combining alcohol with diuretics may cause reduction in blood pressure, possibly resulting in dizziness when a person stands up.

☐ PSYCHOTROPICS
(Tindal, Mellaril, Thorazine, etc.)

Alcohol and the "major tranquilizers" cause additional depression to central nervous system function, which can result in severe impairment of voluntary movements such as walking or using the hands. The combination can also cause a loss of effective breathing function and can be fatal.

☐ SEDATIVE HYPNOTICS
(Doriden, Quaalude, Nembutal, etc.)

Alcohol in combination further reduces the function of the central nervous system, sometimes to the point of coma or the loss of effective breathing (respiratory arrest). This combination can be fatal.

☐ SLEEP MEDICINES

It is likely that non-prescription sleeping medicines, to the degree that they are effective, will lead to the same kind of central nervous system depression when combined with alcohol as the minor tranquilizers (See below).

☐ TRANQUILIZERS - MINOR
(Miltown, Valium, Librium, etc.)

Tranquilizers in combination with alcohol will cause reduced functions of the central nervous system, especially during the first few weeks of drug use. This results in decreased alertness and judgment, and can lead to household and automotive accidents.

☐ VITAMINS

Continuous drinking can keep vitamins from entering the blood stream. However, this situation changes when a person stops drinking.

☐ OTHER

Either we have not been able to identify the drug you mentioned, or data are not sufficient to provide an answer. Check with your doctor or pharmacist to be sure.

DOs AND DON'Ts OF WISE DRUG USE

DO:

Ask questions
Something daily that helps relax
Check with doctor - how long to take prescription
Tell doctor about other medicines, over the counter drugs and special diets
Eat properly - drink plenty of water
Exercise daily
Ask pharmacist about generic drugs, drug interactions, and prescription expiration date
Follow doctor's directions
Ask doctor for a simple drug taking schedule to fit daily activities
Let doctor know of any/all side effects, symptoms and allergies
Ask for easy-open caps

DON'T:

Drink alcohol when taking medicine
Drink alcohol to make you feel better
Stop taking medicines without doctor's advice
Stop taking medicines because you feel better
Take vitamins without telling your doctor
Use over the counter drugs regularly or for long periods
Take medicines in the dark
Share medications with others
Use old prescriptions
Dismiss side effects as signs of "old age"
Mix medicines in one bottle or transfer from one to the other

QUESTIONS TO ASK DOCTOR/PHARMACIST

1. What is being prescribed?
2. What is it supposed to do?
3. How will it make me feel?
4. How long do I take it?
5. What food or medications can/can't I take with new prescription?
6. How do I take it?
   with/without water
   with/without food
   before, after or with meals
7. How often?

Medicare will pay for a second opinion. This includes diagnostic tests and test readings - does not cover consultation fee. For information call toll free 1-800-225-6400.

EVALUATIVE MATERIAL

"SUBSTANCE USE AND OLDER PERSONS"

PRESENTER'S APPRAISAL

Senior Center _____

Center Supervisor _____

Dates _____

Attendance by Date _____

Average Attendance _____

Suggestions _____

Overall Impression _____

sfa
3/80

"SUBSTANCE USE and OLDER PERSONS"

SERVICE PROVIDER'S EVALUATION

I. TRAINING SESSION:

1. Overall presentation

1	2	3	4	5
Very informative				not informative at all

2. Material was

1	2	3	4	5
Useful				not useful

3. Delivery was

1	2	3	4	5
Clear				not so clear

II. CONSULTATION: ( ) DATE

1. Was it or was it not hepful? Please Explain:

_____

_____

_____

_____

_____

_____

III. PRESENTATION: ( ) DATES

1. Overall Presentation

1	2	3	4	5
Very informative				not informative at all

2. Material was

1	2	3	4	5
useful				not useful

3. Delivery was

1	2	3	4	5
clear				not so clear

4. Rate the impact of the presentation or participants at your Center

1	2	3	4	5
a lot				not at all

IV. 1. Did you learn anything new? _____ If so, please list 3 things that stick out in your mind the most:

a.) _____

b.) _____

c.) _____

2. How would you improve the program?

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

3/31/80

PARTICIPANT PRE and POST QUESTIONNAIRE

1. Do you ask your doctor questions about your health or your prescribed medicines? _____Yes _____No

2. Do you tell your doctor everything he or she needs to know about your health?
   a. About side effects of medicines? _____
   b. About over the counter drugs that you are taking? _____
   c. About other prescribed medicines that you are taking? _____

3. Name 3 medications that your doctor has prescribed for you in the past 6 months.

   _____

   _____

   _____

4. Do you know what generic drugs are? _____ Yes _____No

5. Do you use generic drugs? _____ Yes _____No

6. Do you know what a drug interaction is ? _____

7. Do you know an older person who drinks beer, wine or whiskey? _____

8. How do you feel when you see an older person drunk?

   _____

9. It is harmful to drink alcohol when you are on medication? _____

10. Are these items drugs?

Vitamins	_____Yes	_____No
Alcohol	_____Yes	_____No
Geritol	_____Yes	_____No
Caffeine (Coffee or Tea)	_____Yes	_____No
Rolaids	_____Yes	_____No
Valium	_____Yes	_____No
Nicotine (Cigarettes, Pipes, Cigars).	_____Yes	_____No

12. Do you swap medications with family or friends? _____Yes _____No

52

4/80 lam/sa

FOLLOW - UP

Follow-up materials include:

(1) a 3-part article to be used as a handout or incorporated into newspapers, monthly newsletters, etc.

(2) Center Presentation Handouts (pp. 36-39)

(3) Brochure, "Be Responsible for Your Own Health" (attached)

PART I

We live in a time when medical advances are happening faster than at any time in the past. Only 10 years ago, less than half the medicines now in use were on the market. Partly because of the new drugs, more people live longer, they are healthier, and they are more independent than in past generations. Today's older people in particular benefit from the new medicines.

But with these benefits come risks. Drugs are powerful substances - and if they are not used carefully, the consequences can be serious. Drugs can effect different people in different ways. People can sometimes forget whether or not they took a medicine. They have trouble keeping track of what to take and when. Because seniors generally take more medicines than anyone else, they naturally run a greater risk of having problems with drugs.

But these risks can be avoided. If you know how to prepare for a visit to your doctor, what questions to ask, how to take medicines, and what side effects to watch out for, you can cut down the risk of having bad reactions.

TAKING RESPONSIBILITY FOR YOUR OWN HEALTH CARE

In this world of medical specialists, advanced technology, and new medicines that act in ways you don't understand, you - the patient - still must make the major decisions about your own health. You are not alone, of course, for your doctors, pharmacists and other health professionals are there to help you. But how you use their advice is up to you.

There are many decisions for you to make and responsibilities for you to take about your health care and the medicines you take. One of these responsibilities is giving and receiving information when you visit the doctor. Doctors and patients are partners. The doctor depends on the patient for basic information. And the doctor's advice is good only if the patient follows it. As soon as you, the patient, leave the doctor's office, you are in charge of obtaining your medicines, taking them according to instructions, and paying attention to the results. You have a need - and a right - to know how to do this properly.

As a patient, you wear two hats. First, you are a person seeking help because you are sick. Your task here is to tell the doctor what he or she needs to know and submit to an examination. Second, as the person who must manage you own health care plan, you must learn as much as you can about your state of health and about the medicines prescribed for you. If you do not get full, clear

instructions, the best medical opinion may be of little help.

PREPARING FOR THE DOCTOR'S VISIT - WHAT TO BRING

As the doctor's partner, you should tell the doctor all he or she needs to know in order to diagnose your problem and prescribe the proper medicines. Think about the office visit beforehand - and while you do, prepare a written list of things to tell the doctor and questions you want to ask.

The following is a list of questions to take to the doctor's office:

1. What is being prescribed?
2. What is it supposed to do?
3. How will it make me feel? Will there be any side effects?
4. How long do I take it?
5. What food or medications can/can't I take with the new prescription?
6. How do I take it?
   - with/without water
   - with/without food
   - before, after or with meals
7. How often?

Also, when you go to the doctor's bring all the medicines you are using, or - if it is easier - bring a written list of all of them. Include the drugs you take that do not require a prescription, such as aspirin or laxatives. Every doctor you see needs to know what will cause a bad reaction when taken together with your other medicines. One drug might harmfully reduce or increase the effects of another, or the combination of 2 drugs may produce a new and dangerous reaction.

You should also bring a written list of all your allergies and the medicines you have had a negative reaction to.

PART II

GETTING INFORMATION ABOUT MEDICINE FROM YOUR PHARMACIST

After you receive a prescription from your doctor, you take it to the pharmacist to have it filled. The pharmacist is an expert on drugs and their effects. He or she can provide you with valuable information on:

*side effects of prescription and over-the-counter medicines
*how to get easy-to-open caps rather than the difficult child-proof caps on your medicines
*how to save money on drugs

When you buy over-the-counter drugs, ask your pharmacist how they might interact with other drugs you are taking. All drugs have effects on your body. Your pharmacist can help you prevent problems, if you ask.

RECOGNIZING AND REPORTING SIDE EFFECTS

Your responsibility for your own health care doesn't end with getting instructions and developing a good system for taking medicines. To stay as healthy as possible, you should pay attention to how your own body responds to medicines and be sensitive to side effects.

Why? When you take several drugs each day, you might experience unusual combination effects. One drug may neutralize or strengthen the effect of another. Some of these interactions can cause problems. Further, when a person ages, his or her body may absorb the drugs differently than when he or she was younger. Just as an elderly person usually needs less food than a younger person needs, he or she may need less medicine.

In most cases, if medicines act on your body in negative ways, your doctor can prescribe substitute drugs or drug combinations that can do as good a job without the bad side effects. However, before the doctor can make such decisions, you must gather and report the information to him or her.

In some case, a prescribed medicine will have an unavoidable side effect for most users. For example, some muscle relaxants make the patient feel drowsy. At this stage of medical science, there may be no alternative drug available. You need to be aware of such side effects and take them into account in your plans each day.

Do not believe that adverse effects of medications are necessarily "natural", especially for older people. This may be so in a given case, but the judgment should be made by your doctor.

To reduce the risk of adverse effects from medicines, we recommend the following:

*At every visit to the doctor, inform him or her of all the other medicines - including non-prescription drugs - you are taking.
*When the medicine is prescribed, ask the doctor what you should expect to feel.
*Take medicines as directed.
*Be aware, beforehand, of what to do if anything goes wrong in taking medicines.

PART III

GENERIC DRUGS

Medicines are often expensive - and paying for them can be a problem, especially for seniors who are on fixed incomes or who take several drugs regularly. But there may be a way for you to save some money on your prescriptions. If your doctor agrees, have them filled with generic drugs instead of brand-name drugs. Generic drugs are often considerably less expensive than their brand-name equivalents.

What is a generic drug? Acetylsalicylic acid is a long, complicated chemical name for a drug that relieves headaches - aspirin is the generic name of this drug and Bayer is the brand name for the drug. Some drugs are available under the generic name as well as one or more brand names; others are available only under a brand name. Your doctor or pharmacist can tell you whether your medicines can be bought under their generic name at lower cost.

To get more information about generic drugs ask your doctor or pharmacist. Most doctors are informed about generic drugs and can tell you whether there is a generic equivalent for any drug you are taking. It is your pharmacist's business to know drugs - and drug manufacturers. Your pharmacist will also know if your State laws permit substitution and can check with your doctor to find out if it's OK to substitute on your prescriptions.

DOs and DON'Ts

Finally, here is a list of the dos and don'ts of wise drug use:

DO:

- Ask questions
- Something daily that helps relax
- Check with doctor - how long to take prescription
- Tell doctor about other medicines, over the counter drugs and special diets
- Eat properly - drink plenty of water
- Exercise daily
- Ask pharmacist about generic drugs, drug interactions, and prescription expiration date
- Follow doctor's directions
- Ask for a simple drug taking schedule to fit daily activities
- Let doctor know of any/all side effects, symptoms and allergies
- Ask for easy open caps

DON'T

Drink alcohol when taking medicine
Drink alcohol to make you feel better
Stop taking medicines without doctor's advice
Stop taking medicines because you feel better
Take vitamins without telling your doctor
Use over the counter drugs regularly or for long periods
Take medications in the dark
Share medications with others
Use old prescriptions
Dismiss side effects as signs of "old age"
Mis medications in one bottle or transfer from one to the other

1½ HOUR SUBSTANCE USE MODULE

1½ HOUR SUBSTANCE USE MODULE

The 1½ hour component was condensed from the 3 hour component for use in senior clubs and other community or civic organizations.

AN OVERVIEW: SOME FACTS

* APPROXIMATELY 22 MILLION PERSONS (10%) 65+
* 80-86% SUFFER AT LEAST ONE CHRONIC CONDITION
* CONSUME 25% OF ALL PRESCRIPTION DRUGS
* NO SPECIFIC GERIATRIC DRUG DOSES
* WOMEN CONSUME MORE LEGAL DRUGS THAN MEN
* OLDER WOMEN ALONE ARE AT HIGHEST RISK OR MOST VULNERABLE
* ALCOHOL ABUSE IN OLDER POPULATION PROBABLY EXCEEDS 3 MILLION PERSONS 60+
* PROBLEMS OF ABUSE USUALLY UNDETECTED
* 1 TYPE OF ALCOHOL ABUSE IS THE REACTIVE KIND-DEVELOPED AS A COPING MECHANISM
* ALCOHOL ABUSE MAY MASK OTHER PROBLEMS I.E., DEPRESSION
* WIDOWERS ARE THE HIGHEST RISK GROUP FOR ALCOHOL ABUSE

(BRAINSTORMING SESSION):

QUESTION: HOW DOES THE BODY CHANGE WITH AGE?

BODY CHANGES ASSOCIATED WITH AGING

CHANGES	RISKS
1. Suffer at least one chronic condition	1. Greater drug use increased risk of reaction
2. Reduced circulatory, liver, digestive and kidney functions	2. Adult dosage may be too much-body uses medicine less quickly
3. Decreased rates of excretion metabolism, change of sleeping habits	3. Tendency to misuse OTC's to correct these problems
4. Decreased resistance to stress	4. Increased risk of side effects
5. Changes in vision and hearing	5. Difficulty understanding instructions-risk of taking incorrectly
6. Short-term memory loss	6. Taking incorrect amount, not following doctor's orders

MENTAL STATES OF MIND WHICH INCREASE RISK OF DRUG AND ALCOHOL MISUSE

MENTAL STATE	POSSIBLE PROBLEM
1. Less tolerance for change	1. Tendency to rely on "tried and true" routines that may be ineffective or may delay a needed trip to the doctor
2. Fear of loss of independence	2. Refusal to take drugs
3. Feelings of insecurity, need for reassurance	3. Ritualistic dependence on routine drugs
4. Feelings of uselessness, worthlessness	4. Become more conscious of body and feel a need for medicines
5. Reactions to grief and loss	5. Use or misuse of anti-depressant and mood elevating drugs
6. Feelings of boredom	6. Use of drugs to structure time-overuse of sleeping pills

LIFE SATISFACTION

USE OF LEGAL DRUGS/ALCOHOL TO COPE WITH DAILY LIFE

STRESS

SELF-ESTEEM

SELF CONCEPT

LIFE SATISFACTION

LONELINESS

INACTIVITY

DEATH OF A LOVED ONE

RETIREMENT

LOSS:

(MOBILITY)
(CHANGE OF RESIDENCE)

(CHANGE OF NEIGHBORHOOD)

ISOLATION

FIXED INCOME

NEW ROLES

SOME FACTORS CONTRIBUTING TO MISUSE

* SOCIETY'S GENERAL ACCEPTANCE OF PILLS FOR A CURE-ALL
* OVER PRESCRIBING OF DOCTORS
* LACK OF RE-EVALUATION OF MEDICINES
* FIXED INCOME
* FEAR OF DOCTORS
* LACK OF INFORMATION
* THOSE WHO ABUSE ALCOHOL DENY THEY HAVE A PROBLEM-THIS IS DONE ALSO BY FAMILY, MEDICAL PROFESSIONALS
* MYTH OF UNTREATABILITY FOR ALCOHOLICS

(BRAINSTORMING SESSION):

QUESTION: WHY DO WE USE DRUGS?

DRUG PROBLEMS

1. OVERUSE

   Taking incorrectly, forgetting-taking another

2. UNDERUSE

   Taking incorrectly, failure to fill prescriptions, discontinuing use, forgetting to take

3. IMPROPER USE

   Failure to follow directions, diet, incorrect storage, use of outdated drugs, failure to notice side effects, duplicate medicines by different doctors, sharing/borrowing of drugs

4. ABUSE

   Habit forming, drug dependency, use for suicide

INTERACTIONS

Drug - Body

Alka-Seltzer - do not use on sodium restricted diet, diabetic, hypertensive and cardiac disorders

Aspirin - nausea - irritation of the lining of the stomach

Tylenol, Bufferin, Aspirin - potential for overdose

Vitamins - potential for overdose

Excessive use of aspirin - tinnitus (ringing of the ear)

Tylenol, Excedrin, Datril, Tempra - substitute for aspirin, may cause allergic reaction i.e., skin rash. Overdose may cause fatal liver damage.

Antihistamines - use with caution with diabetic, hypertensive and cardiac disorders, glaucoma

Diuretics - potassium depletion

The Pill - depletes folic acid and vitamin B_6

Antacids - contains 4 substances: sodium bicarbonate, calcium carbonate, aluminum and magnesium. Excessive use of antacids may have the following effects:

1. calcium carbonate - may accumulate calcium in the blood
2. sodium bicarbonate - excessive amounts of alkali in blood and tissues
3. aluminum - constipates
4. magnesium - diarrhea
5. Phosphate depletion causing muscle weakness; Vitamin D. deficiency
6. In elderly, too much aluminum may lead to intestinal obstruction
7. Antacids high in aluminum can worsen osteoporosis by depleting the phosphate which destroys the body's calcium balance - may ultimately weaken bones.

Diet pills can cause elevation in blood pressure.

Drugs can cause abnormally high or low test results and can lead to false interpretations and ultimately an incorrect diagnosis. Doctor may prescribe an unnecessary drug to treat a non-existent malady. If you have taken any drugs prior to a lab test, you should inform the doctor, nurse or technician.

Drug - Drug

Avoid nicotine, caffeine and antihistamines in combination.

Alcohol in combination with sedatives, valium, tranquilizers, cough medicine - may cause death.

Alcohol in combination with caffeine and nicotine - increased deterioration of performance.

Anticoagulants - do not mix alcohol or any prescription or OTC without doctor's knowledge.

Antacids reduce the effectiveness of aspirin.

Aspirin inhibits the effectiveness of Vitamin C.

Drug - Food

Tetracycline - do not use in combination with dairy products (including cream with coffee) or antacids.

Drinks high in ascorbic acid (soft drinks, fruit or vegetable juices) should not be used in combination with any medication. Acid causes medication to dissolve too quickly into stomach instead of intestines where absorption is better. An exception to this is an iron pill taken with orange juice. The orange juice increases the absorption of the iron.

MAO (monamine oxidase) in combination with aged foods - cheese, wine, beer, salami, pepperoni - should be avoided. May cause headaches, elevated blood pressure, brain hemorrhage or death.

Foods high in Vitamin K, i.e., liver, leafy green vegetables hinder effect of anticoagulants.

Foods with licorice extract from natural source (jelly beans) in excess amounts can cause elevation of blood pressure or counter effects of high blood pressure medicine.

A high carbohydrate meal may slow down the absorption of Tylenol and delay headache relief.

If you want medicines to go to work as fast as possible, drink plenty of water (8 oz.). Skimping on liquids can reduce the amount of drug that gets into your bloodstream by as much as 1/2.

Some drugs can be irritating to the digestive tract. Taken on an empty stomach can cause pain, nausea, vomiting, diarrhea and ulcers. Examples: cortisone, Indocin, arthritis medicine.

Other medicines will be incompletely absorbed if taken within a few hours of a meal. Examples: tetracycline, penicillin, amoxicillin, antibiotics.

Definition of an empty stomach: 1 hour before meal, 2 hours after a meal.

TIPS: DOS and DON'TS

DO:

* ASK QUESTIONS
* TELL DR. ABOUT OTHER MEDICINES, OTC'S, AND SPECIAL DIETS
* ASK PHARMACIST ABOUT DRUG INTERACTIONS
* ASK PHARMACIST ABOUT GENERIC DRUGS
* ASK FOR EASY-OPEN CAPS

DON'T:

* DRINK ALCOHOL WHEN TAKING MEDICINES
* TAKE MEDICINE IN DARK
* USE OTC'S REGULARLY OR FOR LONG PERIODS OF TIME
* DISMISS SIDE EFFECTS AS SIGNS OF "OLD AGE"

4/80

FOUR HOUR ALCOHOL AWARENESS MODULE

FOUR HOUR ALCOHOL AWARENESS MODULE

This component has a 2-fold purpose:

Part I Alcohol Education - a training tool for service providers used for 1-hour in-service training program.

Part II Alcohol Use, Misuse, Abuse - educational device for residents of an adult home who were exposed to the program over a 2-day period, 1 - 1½ hours per session.

PART I

ALCOHOL EDUCATION

1. ALCOHOL

2. ALCOHOL and DRUG INTERACTIONS

3. ATTITUDES and VALUES AROUND ALCOHOL (pre-test)

4. SOCIAL USE TO ADDICTION

5. EFFECTS OF ALCOHOL ON BODY

6. ALCOHOL RELATED PROBLEMS

7. ATTITUDES and VALUES AROUND ALCOHOL (post-test)

8. HOW TO DEAL WITH THE INEBRIATED and/or ALCOHOLIC PERSON

9. SO, WHAT DO YOU DO?

ALCOHOL:

WHAT IS ALCOHOL?

ALCOHOL IS A DRUG. IT'S THE INTOXICATING INGREDIENT IN ALCOHOLIC BEVERAGES.

BEER is alcohol!

ALE is alcohol!

WINE is alcohol!

HARD LIQUOR is alcohol!

ALCOHOL and DRUG INTERACTIONS

(Antipsychotics)

		THORAZINE		
		HALDOL		
ALCOHOL	+	PROLIXIN	=	INCREASED CNS DEPRESSION
		MELLARIL		

(Tranquilizers)

		LIBRIUM		
		VALIUM		

- - - - - - - - - - - - -

(Anti-depressants)

		TOFRANIL		
ALCOHOL	+	ELAVIL	=	MAY INCREASE DANGER OF ACCIDENTAL OVERDOSE
ALCOHOL	+	STELAZINE	=	INTENSIFICATION AND PROLONGATION OF CNS DEPRESSION
ALCOHOL	+	HALDOL	=	MAY RESULT IN HYPOTENSION (LOW BLOOD SUGAR)
ALCOHOL	+	COGENTIN	=	HYPOTHERMIA (LOW BODY TEMPERATURE) and ANHIDROSIS (DEFICIENCY OF SWEAT)
ALCOHOL	+	ANTIBUSE	=	VIOLENT REACTIONS SUCH AS NAUSEA, PALPITATION OF HEART and SEVERE VOMITING

ATTITUDES and VALUES AROUND ALCOHOL (Pre-test)

This exercise can be used to show attitudes and values regarding the use of substances.

For example, "I'm a professional and I certainly don't abuse substances". - Although I smoke heavily, I rank nicotine as a 1 or 2.

- - - - -

How would you rank each of the following substances in degree of harm? i.e., (1) being the least harmful, (6) being the most harmful:

NICOTINE

TRANQUILIZERS

SEDATIVES

ALCOHOL

CAFFEINE

ANALGESICS

SOCIAL USE TO ADDICTION

USE - MISUSE - ABUSE

USE - AT A PARTY YOU HAVE A COUPLE OF DRINKS

MISUSE - AT A PARTY YOU GET DRUNK

ABUSE - GO TO PARTY JUST TO GET DRUNK

- - - -

USE - GO TO FRIEND'S ROOM, WATCH T.V. - HAVE A COUPLE OF BEERS

MISUSE - GO TO FRIEND'S ROOM, WATCH T.V. - DRINK (2) 6-PACKS and GET DRUNK

ABUSE - GO TO FRIEND'S ROOM JUST TO GET DRUNK

EFFECTS OF ALCOHOL ON BODY:

CIRRHOSIS OF THE LIVER, DIABETES, ULCERS, GASTRITIS, DULLED THINKING, LOSS OF MEMORY, SHORTENS LIFE SPAN.

CAUSES MAL-NUTRITION

EFFECTS OF ALCOHOL ON OTHER MEDICAL PROBLEMS:

CAN MASK DEPRESSION

CAN AGGRAVATE OTHER MEDICAL CONDITIONS

CAN RESULT IN WHAT APPEARS TO BE EARLY ONSET OF SENILITY

CAN RESULT IN INJURY and ACCIDENT FOR WHICH YOU MUST BE HOSPITALIZED

ALCOHOL RELATED PROBLEMS:

1. HEALTH PROBLEMS

2. JOB LOSS

3. PERSONAL RELATIONSHIPS SUFFER

   SPOUSE
   CHILDREN
   FAMILY
   FRIENDS

4. PERSONALITY CHANGES

   MOODINESS
   ARGUMENTATIVE - VIOLENCE
   ISOLATION
   LACK OF AMBITION and MOTIVATION
   SEX (LOWERED INHIBITIONS and/or SEXUAL DYSFUNCTION)

ATTITUDES AND VALUES AROUND ALCOHOL (Post-test)

This exercise can be used to show attitudes and values regarding the use of substances.

For example, "I'm certainly aware of the dangers involved when individuals abuse substances, therefore, I would never do that." - Although I smoke heavily, I rank cigarettes as a 1 or 2.

- - - - -

How would you rank each of the following substances in degree of harm? i.e., (1) being the least harmful, (6) being the most harmful.

COFFEE

BEER

CIGARETTES

PHENOBARBITAL

VALIUM

ASPIRIN

HOW TO DEAL WITH THE INEBRIATED and/or ALCOHOLIC PERSON

QUESTIONS

1. YOUR FEELINGS and/or PERCEPTIONS OF A DRUNK

2. HOW DO YOU DEAL WITH THOSE PEOPLE YOU BELIEVE TO BE ALCOHOLICS?

THE TRUTH OF THE MATTER IS - YOU CANNOT DEAL WITH AN INEBRIATED PERSON .

WHY?

THE INEBRIATED PERSON IS OFTEN TIMES BEYOND REASONING, THEIR INHIBITIONS ARE DOWN AND THEY SAY/DO THINGS THEY WOULDN'T ORDINARILY SAY OR DO.

ALCOHOLIC DRINKING LEADS TO CONFUSED THINKING - COMPREHENSION AND UNDERSTANDING IS GREATLY REDUCED.

SO, WHAT DO YOU DO?

BEFORE YOU CAN DO ANYTHING, THE PERSON MUST BE SOBER OR DETOXED.

TALK TO THEM ABOUT THEIR PROBLEM AND THEIR PROBLEMS POSSIBLE RELATIONSHIP WITH ALCOHOL. HELP THEM IDENTIFY SOME OF THE PROBLEMS THEY HAVE WHEN THEY DRINK.

REFERRAL SOURCES

SUBSTANCE ABUSE SERVICES - MENTAL HEALTH CENTER

ALCOHOLICS ANONYMOUS

PASTORAL COUNSELING

DETOX UNIT

MEN'S HOME

PART II

ALCOHOL USE, MISUSE, ABUSE

DAY 1

1. WHAT IS ALCOHOL?
2. MENTAL STATES - PSYCHOLOGICAL and SOCIAL REASONS
3. USE, MISUSE, ABUSE
4. PROGRESSION OF ALCOHOLIC DRINKING
5. PHYSICAL STATES
6. EFFECTS OF ALCOHOL ON BODY
7. ALCOHOL and DRUG INTERACTIONS
8. PROBLEM DRINKING TO ADDICTION

WHAT IS ALCOHOL?

MEDICINE IS A DRUG, SO IS ALCOHOL. IT'S A DRUG THAT SLOWS DOWN THE ACTIVITY OF THE BRAIN.

ALCOHOL IS A DRUG THAT PRODUCES INTOXICATION AND/OR UNCONSCIOUSNESS.

BEER is alcohol !

ALE is alcohol !

WINE is alcohol !

HARD LIQUOR is alcohol !

MENTAL STATES - PSYCHOLOGICAL and SOCIAL REASONS

QUESTION: WHY DO PEOPLE DRINK?

QUESTION: WHEN DO PEOPLE DRINK?

USE, MISUSE, ABUSE

USE - AT A PARTY YOU HAVE A COUPLE OF DRINKS

MISUSE - AT A PARTY YOU GET DRUNK

ABUSE - GO TO PARTY TO GET DRUNK

— — —

USE - GO TO FRIEND'S ROOM, WATCH TELEVISION, DRINK A COUPLE OF BEERS

MISUSE - GO TO FRIEND'S ROOM, WATCH TELEVISION, DRINK (2) 6-PACKS AND GET DRUNK

ABUSE - GO TO FRIEND'S ROOM JUST TO GET DRUNK

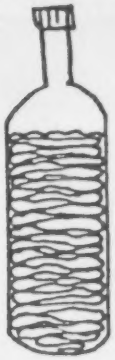
PROGRESSION

OF

ALCOHOLIC DRINKING

1st "SOCIAL"

CONVERSATIONAL; MORE EXPRESSIVE; LESS INHIBITED; SOME LOSS OF COMPETENCY

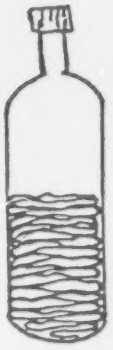


2nd "IRRATIONAL"

SLOWED REFLEXES; IMPULSIVE; BOISTROUS; EXAGGERATED MOOD SWINGS; TENDENCY TO TAKE RISKS

3rd "DISORIENTED"

CONFUSED; TOTTERING; CLUMSY; EASILY PROVOKED/IRRITATED; INARTICULATE; INCONSISTENT IN THOUGHT AND DEED



4th "INEBRIATED"

DRUNK; SLUGGISH; INDIFFERENT; UNAWARE OF SURROUNDINGS; DEBILITATED

5th "PASSED OUT"

UNCONSCIOUS; NON-FUNCTIONING; COMATOSE; RESPIRATIONS MAY BE SERIOUSLY DEPRESSED - CAN PROVE FATAL

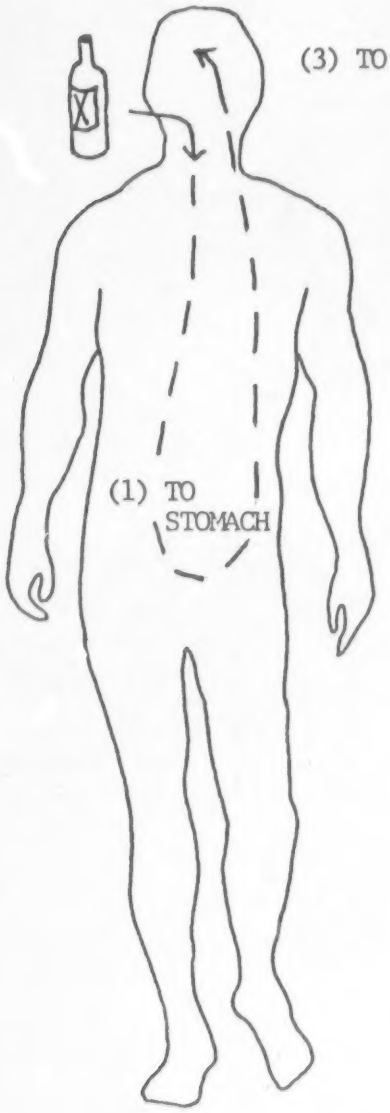
H E A V Y D R I N K I N G

L E A D S T O

A D D I C T I O N !

PHYSICAL STATES

WHAT HAPPENS TO YOUR BODY WHEN YOU DRINK?



(2) 90% GOES TO BLOODSTREAM
10% ELIMINATED THROUGH LUNGS AND KIDNEYS

EFFECTS OF ALCOHOL ON BODY:

STAGGER, FALL, GET SLEEPY, PASS OUT, VOMIT, SLURRED SPEECH

CAUSES MAL NUTRITION

CIRRHOSIS OF THE LIVER, ULCERS, DIABETES GASTRITIS, DULLED THINKING, LOSS OF MEMORY, ENLARGES HEART, SHORTENS LIFE SPAN

ALCOHOL and DRUG INTERACTIONS

(Antipsychotics)

ALCOHOL + THORAZINE, HALDOL, PROLIXIN, MELLARIL = INCREASED CNS DEPRESSION

(Tranquilizers)

LIBRIUM

VALIUM

(Antidepressants)

TOFRANIL

ALCOHOL + ELAVIL = MAY INCREASE DANGER OF ACCIDENTIAL OVERDOSE

ALCOHOL + STELAZINE = INTENSIFICATION AND PROLONGATION OF CNS DEPRESSION

ALCOHOL + HALDOL = MAY RESULT IN HYPOTENSION (LOW BLOOD PRESSURE)

ALCOHOL + COGENTIN = HYPOTHERMIA (LOW BLOOD TEMPERATURE) and ANHIDROSIS (DEFICIENCY OF SWEAT)

ALCOHOL + ANTABUSE = VIOLENT REACTIONS SUCH AS NAUSEA, PALPITATION OF HEART AND SEVERE VOMITING

PROBLEM DRINKING TO ADDICTION

EARLY STAGES

GULPS DRINKS; RELIEF DRINKING TO RELAX, CALM DOWN, SLEEP; INCREASE IN TOLERANCE; FAILS TO KEEP PROMISES MADE ABOUT CONTROLLING DRINKING; DRINKS TO FORGET PROBLEMS

MIDDLE STAGES

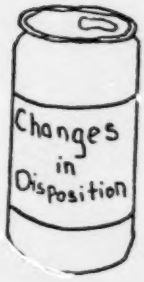
DRINKING ALONE OR AT INAPPROPRIATE TIMES; SNEAKING DRINKS; FAMILY, JOB AND SOCIAL PROBLEMS MAY MULTIPLY

FINAL STAGES

BLACKOUTS; NEGLECTS DIET, HEALTH, PERSONAL APPEARANCE; BENDERS OR BINGES; HALLUCINATES; DELERIUM TREMENS; TOTALLY INVOLVED IN GETTING DRUNK AND STAYING DRUNK

MORE SYMPTOMS . . .

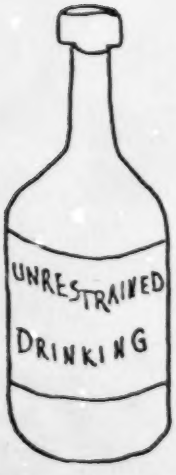
from: life
worries
responsibilities



withdrawn
quarrelsome
anxious
apathetic

spouse
children
friends
employer
significant others

inferiority
superiority
confidence
mood



continuous drinking despite fact that it is no longer enjoyable; cannot imagine life without alcohol

97

ALCOHOL USE, MISUSE, ABUSE

DAY 2

1. RECAP
2. FILM (appropriate film of your own choosing)
3. REACTIONS TO ALCOHOLIC BEHAVIOR
4. ALCOHOL RELATED PROBLEMS
5. MALE/FEMALE DRINKING PATTERNS
6. ALTERNATIVES TO DRINKING
7. WHAT TO DO

RECAP

FILM

REACTIONS TO ALCOHOLIC BEHAVIOR

QUESTION:

WHAT DO YOU THINK OR FEEL WHEN YOU SEE A DRUNK?

PROBLEM AREAS

QUESTION:

WHAT KINDS OF PROBLEMS DOES DRINKING CAUSE?

ALCOHOL RELATED PROBLEMS

1. HEALTH PROBLEMS

2. JOB LOSS

3. PERSONAL RELATIONSHIPS SUFFER

   SPOUSE
   CHILDREN
   FAMILY
   FRIENDS

4. PERSONALITY CHANGES

   MOODINESS
   ARGUMENTATIVE
   ISOLATION
   LACK OF AMBITION, MOTIVATION

MALE/FEMALE DRINKING PATTERNS

ABUSE IN OLDER POPULATION PROBABLY EXCEED 3 MILLION PERSONS 60 YEARS OF AGE AND OLDER.

QUESTION:

WHO ABUSES ALCOHOL MORE, MEN OR WOMEN? . . . and WHY?

ANSWER:

MEN . . . WIDOWERS ARE THE HIGHEST RISK GROUP FOR ALCOHOL ABUSE

AND WHY?

* HISTORICALLY ALCOHOL HAS BEEN MADE MORE AVAILABLE TO MEN
* ALCOHOL USE HAS BEEN MORE SOCIALLY ACCEPTABLE FOR MEN THAN WOMEN
*ALCOHOL ABUSE i.e., "A NIGHT OUT WITH THE BOYS" HAS BEEN MORE SOCIALLY ACCEPTABLE FOR MEN THAN WOMEN

ALTERNATIVES TO DRINKING

CHANGING PEOPLE, PLACES AND THINGS:

- MAKE NEW FRIENDS WHO HAVE OTHER INTERESTS

- AVOID THOSE PLACES WHERE DRINKING TAKES PLACE

- DEVELOP NEW INTERESTS (HOBBIES, TAKE ADVANTAGE OF COMMUNITY PROGRAMS, TAKE A NEW INTEREST IN YOURSELF)

WHAT TO DO:

1. RECOGNIZE THAT THERE IS A PROBLEM

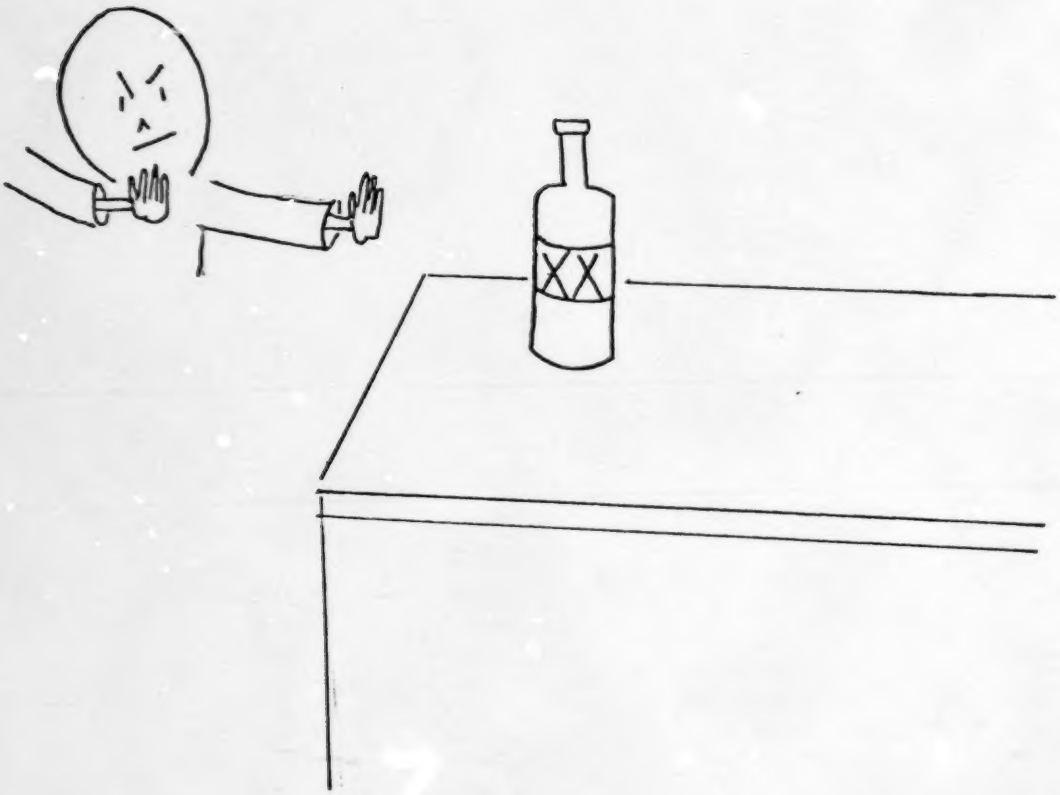
2. TALK OVER PROBLEM WITH SOMEONE ELSE

3. SEEK ASSISTANCE

   COUNSELOR
   THERAPIST
   ALCOHOLICS ANONYMOUS
   MEDICAL DOCTOR

"HEAVY DRINKING LEADS TO ADDICTION"

104



RESPONSIBLE DECISION MAKING